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Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade
Chemical Review Committee
Fifth meeting
Rome, 23–27 March 2009
Item 4 (b) (ii) of the provisional agenda*

Listing of chemicals in Annex III to the Rotterdam Convention: review of notifications of final regulatory actions to ban or severely restrict a chemical: endosulfan

Endosulfan

Note by the Secretariat

Addendum

Supporting documentation provided by Burkina Faso, Cape Verde, Gambia, Mali, Mauritania, Niger and Senegal

The Secretariat has the honour to provide, in the annex to the present note, documentation received from Burkina Faso, Cape Verde, Gambia, Mali, Mauritania, Niger and Senegal to support their notification of final regulatory action on endosulfan as a pesticide.

* UNEP/FAO/RC/CRC.5/1.

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Annex

1. Decision to ban endosulfan by the Permanent Interstate Committee for Drought Control in the Sahel (13/11/2007);
2. Assessment of the risks for surface and ground waters pollution by pesticides used in cotton production in Burkina Faso (Adama TOÉ1, Ray CORRELL, Rai KOOKANA ,Ros MILLER)
3. Examination of pesticides for conversion from provisional sale authorization to registration (Mission Report 2007, Permanent Interstates Committee For Drought Control in the Sahel)
4. The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels - Final Review Report and Regulatory Decision-Review Series 2 June 2005, Australian Pesticides & Veterinary Medicines Authority (APVMA)
5. Re-registration Eligibility Decision for Endosulfan (US Environmental Protection Agency, Prevention Pesticides Toxic Substances (7508C), EPA 738-R-02-013, November 2002)
6. Review of Endosulfan, August 1998, Volume 2, National Registration Authority for Agriculture and Veterinary chemicals (NRA, Australia)

The following information is not annexed to the present document and will be made available at the meeting:

7. At the URL http://www.inchem.org/documents/ehc/ehc/ehc40.htm you can download the Environmental Health Criteria 40: Endosulfan (IPCS)
8. At the URL www.inchem.org/documents/pds/pdsother/class.pdf you can download the: The WHO Recommended Classification of Pesticides by Hazard

BAN ON ENDOSULFAN

Having regard to the revised version of the Common Regulation for Pesticide Registration of the CILSS (Permanent Inter-State Committee on Drought Control) Member States, resulting from Resolution N° 08/34/CM/99 adopted in 1999 in N'Djamena, Chad, by the CILSS Council of Ministers;

Concerned with the protection of human and animal health as well as with the environment;

On the proposal of the Sahelian Pesticide Committee submitted at its working session on the 8th May 2007 in Bamako,

The use of Endosulfan in agriculture is prohibited in CILSS Member States for the reasons stated in the enclosed document.

Taking into account agricultural specificities and the time needed to use up all existing stocks, the decision taken by the coordinating minister on the recommendation of the Sahelian Committee to ban this pesticide enters into force on the date of the signature as for its distribution and on 31st December 2008 as for its use.

The present decision will be communicated wherever necessary.

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Minister Coordinator of CILSS
Minister of agriculture and breeding
Islamic Republic of Mauritania
Ampliations
- Executive Secretary of CILSS (Original)
- Institut du Sahel (CSP)
- Regional center Agrhvmet

Annex to the decision to ban Endosulfan

Endosulfan is an organochlorine insecticide/acaricide. It is composed of isomers a and b whose main metabolite, Endosulfan sulfate, is more toxic and persistent than Endosulfan itself. Endosulfan is highly, acutely toxic (class Ib, i.e. highly toxic) and the risk of intoxication under Sahelan conditions is unacceptable.

Endosulfan is used to control pests and cotton mites following the high recrudescence of Elicoverpa armigera in 1996 and its resistance to pyrethroids. Huge quantities of the product have been used ignoring good agricultural practices and with serious risks for human health and the environment. It is applied twice during the farming season in the Sahel at doses between 300 and 750 gr. of active ingredient per hectare. It is applied with a terrestrial sprayer (rotating disc sprayer or engine-driven portable sprayer). The application is carried out by farmers without adequate protection.

Comparing the product applications in Australia and in the Unites States of America and the decisions taken in Europe and France, the following can be observed:

- The use of Endosulfan is severely restricted in Australia. The product is only used by authorized people. The use of complete protective clothing is required during sprayer filling and terrestrial application (waterproof protective clothing, long sleeve PVC gloves, waterproof boots and complete respiratory mask (full- face mask) or safety goggles with half-mask respirator.

- In the United States, Endosulfan has been registered for cotton trees. Having been assessed that the risk of worker exposure was high, a whole range of measures to reduce the risk has been adopted. These included a suit over a long-sleeve shirt and trousers, chemical resistant shoes and boots, waterproof gloves, waterproof overall for sprayer filling and a respiratory mask against organic vapor.

  Endosulfan is not authorized in France in chemical formulations approved for marketing. The opinion published on the Official Gazette of 22nd February 2006 withdrew marketing authorizations for plant protection products containing Endosulfan for all agricultural and non-agricultural uses, with the following time period during which existing stock had to be used up:

  - until 31st December 2006 for its distribution,
  - until 30th May 2007 for its use.

Endosulfan is prohibited in the European Union following the review concerning the entry in Annex I (positive list) of Directive 9L/4I4/EEC pursuant to Community ruling 2OO5/864/EC of 2nd December 2005.

The European Union refused to enter Endosulfan in Annex I because it did not meet minimal safety requirements, particularly with regards to its impact on the environment and its toxicological profile.

Although application doses are similar to those used in the Sahel, required protection clothing is neither available nor is it adequate for local conditions (heat). The training level of farmers in the Sahel is far below that of American and Australian farmers. Furthermore, it should not be forgotten that many dwellings in the Sahel are surrounded by cotton fields.

In the Sub-Saharan region, cases of intoxication have been reported in Benin and in Senegal. Endosulfan residues have been found in peanut oil in Senegal. Endosulfan is highly toxic for fish and some aquatic invertebrates. The adverse impact on aquatic ecosystems due to the contamination of surface water in cotton-tree areas in the Sahel is considered to be inacceptable.

A Risk-assessment study of pesticides used on cotton-trees has been carried out in Burkina Faso in 2003 to evaluate their impact on surface waters. According to the Pesticide Impact Rating Index, Endosulfan was the only one among all pesticides used for foliar application having been reported as having a high risk of contaminating surface waters.

Similar studies have been carried out in the Unites States of America where buffer zones are required. The use of Endosulfan is prohibited in areas where surface waters are abundant and potentially vulnerable.

In cotton-trees areas in the Sahel, surface waters are environmentally important. The buffer zones required in the Unites States are not respected in the Sahel.

The use of Endosulfan in the CILSS Member States is no longer justified since other valid alternatives to effectively control Helicoverpa armigera exist and are authorized by the Sahelan Pesticide Committee.

COMITE PERMANENT INTER-ETATS DE LUTTE CONTRE LA SECHERESSE DANS LE SAHEL

PERMANENT INTER-STATE COMMITEE FOR DROUGHT CONTROL IN THE SAHEL

اللجنة الدائمة المشتركة لمكافحة آثار الجفاف في الساحل

-1-0691

N° _____/ MAE

Nouakchott, le 13 NOV 2007 : انواكشوط في

Le Ministre Coordinateur

الوزير المنسق

DECISION N° / MC/ 2007
INTERDICTION DE L'ENDOSULFAN

Vu la version révisée de la Réglementation Commune aux États membres du CILSS sur l'Homologation des Pesticides issue de la Résolution n°08/34/CM/99 prise par le Conseil des Ministres du CILSS en 1999 à N'Djamena, Tchad.

Soucieux de la protection de la santé humaine, animale et de l'environnement ;

Sur proposition du Comité sahélien des pesticides en sa séance de travail du 08 mai 2007 à Bamako.

L'endosulfan est interdite en agriculture dans les Etats membres du CILSS pour les raisons énoncées dans le document joint en Annexe.

En tenant compte des spécificités agricoles et des délais d'utilisation des stocks existants, cette décision d'interdiction prise par le Ministre Coordonnateur sur recommandation du Comité sahélien des pesticides prend effet pour compter de sa date de signature pour la distribution et le 31 décembre 2008 pour l'utilisation.

La présente décision sera communiquée partout où besoin sera.

Nouakchott, le

Le Ministre Coordonnateur du CILSS

وزارة الزراعة والحيوانات — الوزير — Le Ministre — R.I.M - Ministère de l'Agriculture et de l'Elevage

Issagha Correra
Ministre de l'Agriculture et de l'Elevage
République Islamique de Mauritanie

Ampliations

- Secrétariat Exécutif du CILSS (Original)
- Institut du Sahel (CSP)
- Centre Régional Agrhymet

Annexe à la Décision d'interdiction de l'endosulfan

L'endosulfan est un insecticide/acaricide de la famille des organochlorés. Il est composé des isomères α et ß dont le principal métabolite, le sulfate d'endosulfan est plus toxique et plus persistant que l'endosulfan.

L'endosulfan possède une toxicité aigue élevée (Classe Ib c'est-à-dire très toxique) et le risque d'intoxication des utilisateurs dans les conditions sahéliennes est inacceptable.

L'endosulfan est utilisé contre les insectes et les acariens du cotonnier suite à la grande recrudescence de *Helicoverpa armigera* en 1996 et à sa résistance aux pyréthrinoïdes. De grandes quantités de ce produit ont été utilisées sans respect des bonnes pratiques agricoles engendrant de sérieux risques pour la santé humaine et l'environnement. Au Sahel, il est appliqué deux fois durant la saison agricole à des doses comprises entre 300 et 750 g de matière active à l'hectare à l'aide de pulvérisateurs terrestres (appareils à disque rotatif ou appareils pneumatiques à dos). L'application est effectuée par les paysans sans protection adéquate.

En comparant les applications de ce produit en Australie et aux Etats-Unis d'Amérique et les décisions en Europe et en France, nous retenons ce qui suit :

- En Australie, l'utilisation de l'endosulfan est strictement réglementée. Le produit est utilisé uniquement par des personnes autorisées. Le port de vêtement de protection complet est exigé pendant le remplissage des pulvérisateurs et l'application terrestre (vêtements de protection imperméables, gants à manche longue en PVC, bottes imperméables et respirateur complet (masque visage complet) ou lunettes de protection avec respirateur à demi masque.

- Aux Etats Unis, l'endosulfan a été homologué sur le cotonnier. Durant cette période, il avait été reconnu que le risque d'exposition des travailleurs était élevé. Par conséquent, toute une série de mesures de réduction de risques avait été instaurée. Ces mesures incluaient le port d'une combinaison au dessus d'une chemise à manches longues et un pantalon, des chaussures et des bottes imperméables aux produits chimiques, des gants imperméables, un tablier imperméable pour le remplissage du pulvérisateur et un masque respiratoire contre les vapeurs organiques.

- En France, l'endosulfan n'est pas autorisé dans la composition de préparations bénéficiant d'une autorisation de mise sur le marché. L'avis paru au Journal Officiel du 22 février 2006 retire les autorisations de mise sur le marché des produits phytopharmaceutiques contenant l'endosulfan, pour tous les usages agricoles et non agricoles, avec un délai d'écoulement des stocks :

    - jusqu'au 31 décembre 2006 pour la distribution,
    - jusqu'au 30 mai 2007 pour l'utilisation.

Pour l'Union Européenne l'endosulfan est interdite à la suite de l'examen relatif à l'inscription à l'annexe I (liste positive) de la directive 91/414/CEE, en application de la décision communautaire 2005/864/CE du 2 décembre 2005. Ce refus de l'Union Européenne d'inscrire l'endosulfan à l'annexe 1 est dû au fait qu'il ne satisfait pas les exigences sécuritaires minimales en particulier l'effet sur l'environnement et le profil éco toxicologique.

Bien que les doses d'application soient comparables à celles utilisées au Sahel, les équipements de protection requis ne sont ni disponibles, ni appropriés à cause des conditions locales (chaleur). Le niveau de formation des paysans au Sahel est bien en deçà de celui des paysans américains ou australiens sans oublier le fait que certaines habitations au Sahel sont entourées par les champs de cotonniers.

Dans la sous région, des cas d'intoxication ont été rapportés au Bénin et au Sénégal. Des résidus d'endosulfan ont été trouvés dans l'huile d'arachide au Sénégal.

L'endosulfan est très toxique pour les poissons et pour certains invertébrés aquatiques. L'impact négatif sur les écosystèmes aquatiques dû à la contamination des eaux de surface dans les zones cotonnières au Sahel est considéré comme inacceptable. Une étude d'estimation des risques des pesticides utilisés sur le cotonnier pour les eaux de surface a été effectuée au Burkina Faso en 2003. Sur la base du Pesticide Impact Rating Index (Index de classement des pesticides selon leur impact), l'endosulfan était le seul pesticide de tous les pesticides utilisés en application foliaire ayant un risque très élevé de contamination des eaux de surface.

Des études similaires sont rapportées aux Etats-Unis d'Amérique où des zones tampons sont exigées. L'utilisation de l'endosulfan est interdite dans les régions où les eaux de surface sont abondantes et potentiellement vulnérables.

Dans les zones cotonnières au Sahel, les eaux de surface sont importantes sur le plan écologique. Les zones tampons comme exigées aux Etats-Unis ne sont pas encore respectées au Sahel.

L'emploi de l'endosulfan ne se justifie plus dans les pays membres du CILSS car d'autres alternatives capables de lutter efficacement contre l'Helicoverpa armigera existent et sont autorisés par le Comité sahélien des pesticides.

Assessment of the risks for surface and ground waters pollution by pesticides used in cotton production in Burkina Faso:

Evaluation des risques de pollution des eaux de surface et des eaux souterraines par les pesticides utilisés en culture cotonnière au Burkina Faso

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Summary

Cotton is the most important export product of Burkina Faso and the principal source of economic growth. But the cotton production uses a huge amount of pesticides. Several studies and reports have shown there is non-compliance with the Good Agricultural Practices (GAP) by the farmers. The soils are fragile, containing low organic matter, and are subject to erosion. This results in a potential for the contamination of surface water both through direct runoff and through soil erosion. In addition, the situation is compounded by the high rainfall intensities experienced during the wet season.

In spite of this potential threat on water resources related to the pesticides used in such conditions, few studies have been undertaken to assess it. This work describes the first assessment of the risks both on surface and ground water related to the pesticides used in cotton production in Burkina Faso. The primary tool used is a software package “Pesticide Impact Ranking Index”(PIRI) which has been developed by CSIRO. PIRI is used to quantify the pollution and toxicological impact by pesticides on the environment by ,:

- Ranking pesticides in terms of their relative pollution to ground water and/or surface water;
- Comparing different land uses in a catchment or at a regional scale in terms of their relative impact on water quality.

The application of PIRI to pesticides used in Burkina Faso on cotton production shows the following results:

- The pesticides used for weed control and for seed protection are ranked of low risk impact. They don’t represent a prominent threat either for surface water or for ground water for the conditions of their use in Burkina Faso;
- The pesticides used as insecticides in foliar spraying. For the impact of all the insecticides on the surface water, only the use of endosulfan is the greatest potential threat to the surface water. The other products don’t represent a big threat except in the situation of soils of low organic matter content and of crops near surface water. For the impact of all the insecticides on the ground water, all the products are rated at a very low risk impact except benfuracarb which is rated at an Exceedingly High risk impact in situations of soils of very low organic matter content. The overall risk remains non-significant for ground water.

Based on these case studies, the authors propose an Environmental System Management that has the potential to reduce or minimize these risks and to protect the important asset of natural water resources in Burkina Faso.

Résumé

Le coton est le plus important produit d'exportation du Burkina Faso et la principale source de croissance économique. Mais la production cotonnière utilise une grande quantité de pesticides. Plusieurs études et rapports ont montré qu'il n'y a pas un respect des Bonnes Pratiques Agricoles (BPA) par les agriculteurs. Les sols sont fragiles contenant une faible matière organique et sont sujets à l'érosion. Cela se traduit par un potentiel de contamination des eaux de surface à la fois à travers le ruissellement et l'érosion. De plus, la situation est compliquée par les fortes intensités de pluies durant la saison humide.

Malgré cette menace potentielle sur les ressources en eau liée à l'utilisation des pesticides dans de telles conditions, peu d'études ont été entreprises pour l'évaluer. Ce travail décrit la première évaluation des risques à la fois pour les eaux de surface et les eaux souterraines liés à l'utilisation des pesticides en production cotonnière au Burkina Faso.

L'outil primaire utilisé est un logiciel appelé "Pesticide Impact Ranking Index"(PIRI) ou "Index de classement des pesticides selon leur impact" lequel outil a été développé par le CSIRO. PIRI a été employé pour mesurer la pollution et l'impact toxicologique sur l'environnement par des pesticides :

- En classant les pesticides en termes de leur potentiel de pollution relative à l' eau souterraine et/ou à l'eau de surface ; et

- En comparant différentes utilisations de la terre dans une captation ou à une échelle régionale en termes de leur impact relatif sur la qualité de l'eau.

L'application de PIRI aux pesticides utilisés au Burkina Faso le coton montre les tendances globales suivantes :

- Les pesticides utilisés pour le contrôle des mauvaises herbes, et pour la protection des semences sont classés en impact faible. Ils ne représentent une menace proéminente ni pour les eaux de surface ni les eaux souterraines dans leurs conditions d'utilisation au Burkina.

- Les pesticides utilisés comme insecticides en application foliaire. Pour l'impact de tous les insecticides sur les eaux de surface, l'utilisation de l'endosulfan constitue la plus grande menace pour les eaux de surface. Les autres produits ne représentent pas une grande menace excepté les situations de sols à faible taux de matière organique avec des cultures proches des cours d'eau. Pour l'impact de tous les insecticides sur les eaux souterraines, tous les produits sont classés en très faible risque d'impact excepté benfuracarb qui est classé en risque d'impact excessivement élevé seulement pour les situations de sols à très faible taux de matière organique . Le risque global reste non significatif pour les eaux souterraines.

En se basant sur ces études de cas, les auteurs proposent un System de Gestion Environnemental qui a le potentiel de réduire ou de minimiser ces risques et de protéger les valeureuses ressources en eaux du Burkina Faso..

Introduction

Cotton is the most important export product of Burkina Faso and the principal source of economic growth. In 2004-2005, the national production was 632 355 tones of cotton grain on 566 278 ha by more than 325 000 farmers **[1]** .

Cotton has on average contributed 66.5% of Burkina Faso's exports over the last five years. (Source: ONAC Stat. Customs – INSD (2002) quoted by TOE and KINANE**[2]** .

Several studies and reports have shown there is non-compliance with the Good Agricultural Practices (GAP) by the farmers **[3] ; [4] ;[5]** .The soils are fragile, containing low organic matter, and are subject to erosion. This results in a potential for the contamination of surface water both through direct runoff and through soil erosion. In addition, the situation is compounded by the high rainfall intensities experienced during the wet season.

On the whole, pesticides represent real dangers at three (3) levels:

1. Toxicity of the pesticides for the users in agricultural sector and the professionals of plant health industry **[6]; [7]** ;
2. Toxicity for the consumer related to the presence of toxic residues**[8]** ;
3. Pollution and Toxicology of the Environment **[9]** .

To quantify the pollution and toxicology to the environment by pesticides, a software package "Pesticide Impact Ranking Index" (PIRI) has been developed by CSIRO **[10]** .This package:

- Ranks pesticides in term of their relative pollution to ground and/or surface water; and
- Compares different landuses in a catchment or at a regional scale in teirms of their relative impact on water quality .

The present study is an application of PIRI to pesticides used on cotton in Burkina Faso. The main purpose of the study is:

- To evaluate the potential risks of contamination of both surface water and ground water;
- To evaluate the indirects risks to humans and animals using the natural resource in water; and
- To work out a ranking index of the pesticides used in the production of cotton.

Materials and methods

The following resources were used in this study:

- The software package PIRI **[10]** (Appendix 1)
- Data on cotton cultivation (including data on pesticides used and their characteristics (**Table I**)
- Land Use information

We had distinguished 3 groups of pesticides:

Group 1: herbicides

Group 2: fungicides and insecticides for seed protection

Group 3: insecticides in foliar spraying

The land use information for the pesticides of group 1 and 2 (herbicides and seed protection pesticides) differs from that of group 3 in that the ground is bare with no buffer zone and they are applied once a year.

For the pesticides of group 3 (insecticides in foliar spraying) applied many times a year, for the land use information we have had defined 5 scenarios taking into account 4 factors:

- The distance between the field and the water body,
- The width of the buffer zone,
- The number of days between the application and the rainfall;

- The percentage of soil organic matter.

Scenario 1 (**Table II**) is most like the current situation for the pesticides of group 3 (foliar sprayed). Even though there is no special buffer zone managed by the farmers, on the whole the fields of cotton are separated from the sources of water by bush or by other crops not treated with pesticides which can to some extent be considered as a buffer zone. Scenarios 2, 3, 4 and 5 may be considered as rare situations (**Table III**).

Table I Characteristics of insecticides used on cotton

Pesticide	**Classification**	**Spray type**	**Dosage (kg or litres product/ ha)**	**Fraction active ingredient**	**Frequency of application (times/period of interest)**	**Percentage of farm**	**Toxicity (LC50, Rainbow Trout)**	**Sorption**	**Persistence in environment (days)**
Endosulfan	insecticide	Foliar sprayed 240+-20 microns	2	0.35	1	35	0.002	12400	50
Esfenvalerate	insecticide	Foliar sprayed 240+-20 microns	0.5	0.015	1	35	0.00007	5300	35
lambda-cyhalothrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.012	1	35	0.00024	180000	30
Cypermethrin	insecticide	Foliar sprayed 240+-20 microns +	0.5	0.03	1	35	0.00069	100000	30
Chlorpyriphos	insecticide	Foliar sprayed 240+-20 microns	0.5	0.2	1	35	0.003	6070	30
Cyfluthrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.018	1	35	0.006	100000	185
Deltamethrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.01	1	35	0.0009	100000	25
Benfuracarb	insecticide	Foliar sprayed 240+-20 microns	0.5	0.1	1	35	0.037	316	30
alpha-cypermethrin	insecticide	Foliar sprayed 240+-20 microns	0.5	0.015	1	35	0.0028	100000	30
Profenofos	insecticide	Foliar sprayed 240+-20 microns	0.5	0.2	1	35	0.08	2000	8
Dimethoate	insecticide	Foliar sprayed 240+-20 microns	0.5	0.4	1	35	6.2	20	7
Omethoate	insecticide	Foliar sprayed 240+-20 microns	0.5	0.3	1	35	9.1	50	7
Methamidophos	insecticide	Foliar sprayed 240+-20 microns	0.5	0.3	1	35	25	5	6
Pyriproxyfen	insecticide	Foliar sprayed 240+-20 microns	0.5	0.01	1	35	0.325	20142.9	8

Table II Land Use information for Cotton

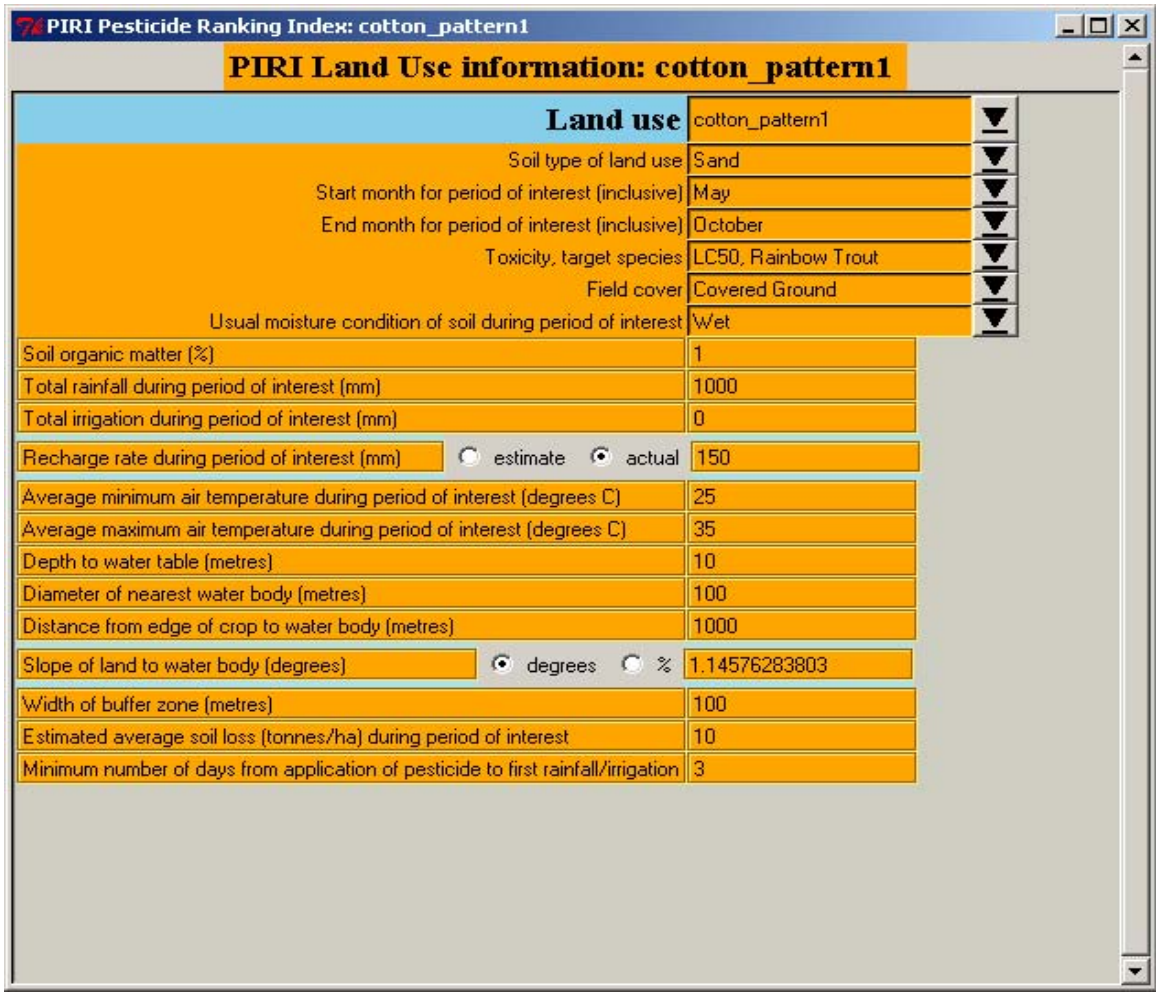

Table III Scenarios considered for the study of pesticides used in foliar application for cotton

	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
Distance between field /water body (m)	1000	100	100	10	10
Width of buffer zone (m)	100	10	10	0	0
Delay between spray and rainfall in days	3	3	0	0	0
soil organic matter(%)	1	1	1	1	0.1

Results and discussion

On the whole, the pesticides used for seed protection (endosulfan, thiram, imidacloprid, metalaxyl, carbendazin and for weed control as herbicides (pendimethalin, paraquat, terbutryn, diuron, prometryn, fluometuron, clomazone) don't represent a major threat either for surface water or for ground water. This is likely related to their conditions of use in Burkina Faso where they are applied once a year **[11]** . In a study based on a probalistic risk assessment method similar low risk of impact for surface water was found for atrazine **[12**].

On the other hand, there is some concern about a few of the pesticides used as insecticides in foliar spraying. According to the scenarios, the results are as follows:

- **Surface water toxicity impact, insecticides.**

On the whole, on taking into account all 5 scenarios**(Table IV)** , we can distinguish according to the results of each individual rating, 5 situations in progressing from the lower risk to the higher risk group:

- A group of 8 pesticides namely, cyfluthrin, deltamethrin, Alpha-cypermethrin, profenofos, dimethoate, omethoate, methamidophos, pyriproxyfen present a very low risk impact irrespective of the scenario considered;
- A second group of 2 pesticides Lambda-cyhalothrin and cypermethrin present a low risk impact whatever the scenario considered;
- Benfuracarb is rated with a low or very low risk impact for the first four scenarios but is rated in the medium risk category for the last scenario.
- A second group of 2 pesticides chlorpyriphos and esfenvalerate move from a very low risk impact with the first scenario to a very high and Exc. High risk (respectively) with the last scenario;
- Endosulfan presents a potential threat whatever the scenario considered. It is always ranked from a high risk impact to an Exceedingly High risk impact (Fig.1).The reasons of the threat to the environment (for surface water) of this organochlorine insecticide that is being used on cotton is due to its dose, and its persistence time. The

amount of endosulfan used on cotton to control insects is normally 700g /ha of a.i., its toxicity (LC50) to rainbow trout is 0.002 mg L^{-1} and it has a persistence in the environment of 50 days.This threat on surface water by endosulfan revealed by PIRI has also been confirmed by the presence of endosulfan residues carried out by GPC-ECD in water samples in the cotton region where this chemical is used **[13].**

Table IV Insecticides rating for surface water on different scenarios of agricultural practice

Pesticides	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
endosulfan	High	High	High	Very high	Ex. high
esfenvalerate	Very low	Low	medium	High	Ex. high
chlorpyriphos	Very low	Very low	Very low	medium	Very high
Lambda-cyhalothrin	Low	Low	Low	Low	Low
cypermethrin	Low	Low	Low	Low	Low
benfuracarb	Very low	Very low	Very low	Low	medium
cyfluthrin	Very low	Very low	Very low	Very low	Very low
deltamethrin	Very low	Very low	Very low	Very low	Very low
Alpha-cypermethrin	Very low	Very low	Very low	Very low	Very low
profenofos	Very low	Very low	Very low	Very low	Very low
dimethoate	Very low	Very low	Very low	Very low	Very low
omethoate	Very low	Very low	Very low	Very low	Very low
methamidophos	Very low	Very low	Very low	Very low	Very low
pyriproxyfen	Very low	Very low	Very low	Very low	Very low

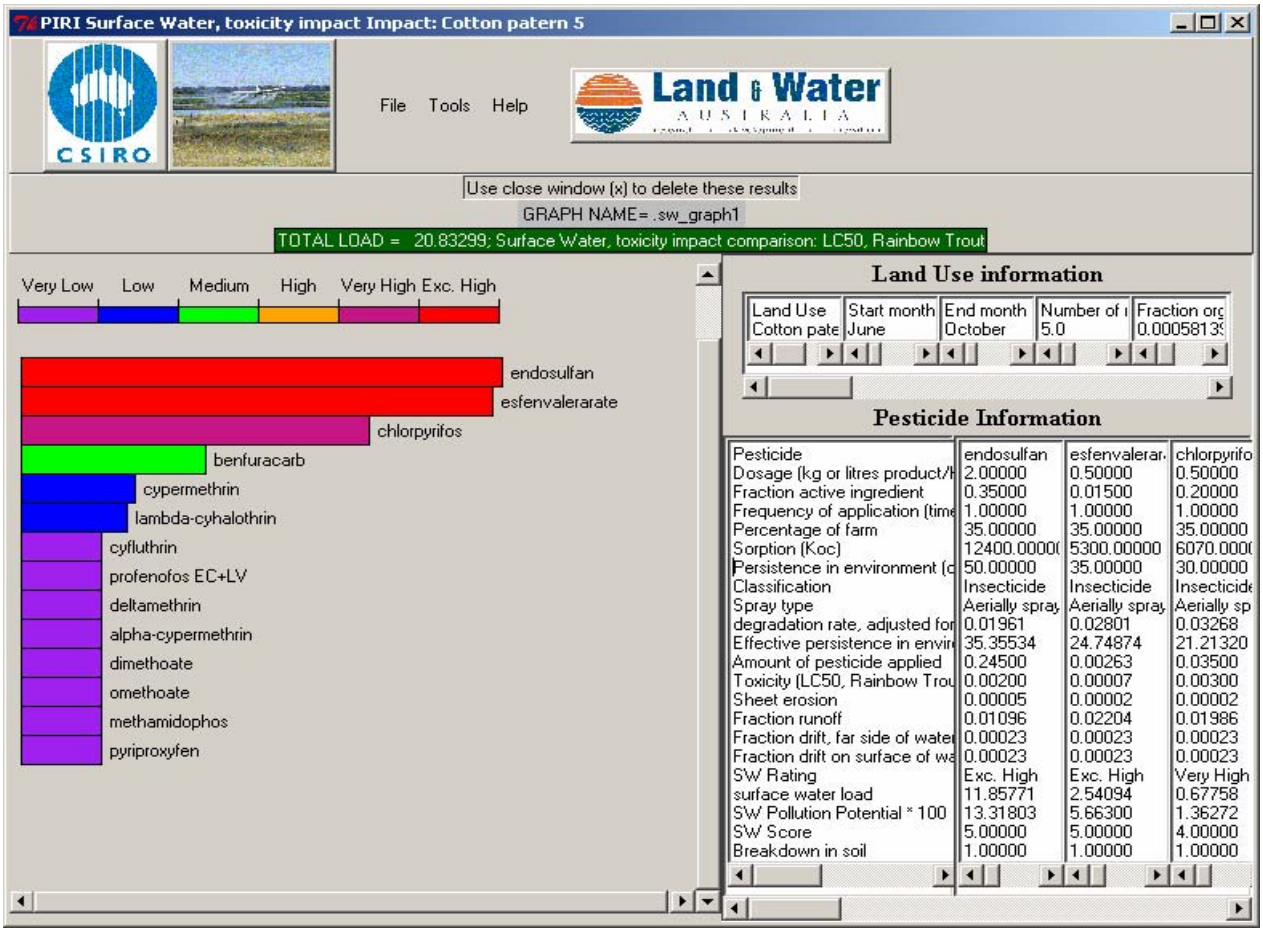

Figure 1 Insecticides used on cotton rated for surface water impact (scenario 5)

- **Ground water toxicity impact insecticides (Table V)**

For the impact of all the insecticides on the ground water, whatever the scenario considered, there is no significant change. All the products are rated at a very low risk impact except benfuracarb which is rated at an Exceedingly High risk impact scenario 5 only (Fig.2). The overall risk remains non-significant for ground water.

The threat on the environment related to the use of pesticides to some extent depends on some factors underlined in our studies. They are:

- the low organic matter content in soil the soil;
- the short distance between the field and the water body;
- the absence of any managed buffer zones;
- the short space of time between the any rainfall and the application of pesticides.

The characteristic of the pesticides is obviously a determining factor.

The low impact of the pesticides as given by PIRI may be distorted depending on the value accorded to the water, because of the mosaic of the crops and of the array of pesticides being used. Pesticides with similar active ingredients are being used, and a more realistic measure of their impact would be the sum of their impacts.

In summary, the key factor susceptible to reducing or increasing the threat of the products to both the surface water and ground water seem to be the soil organic carbon content. For surface water only the buffer zone could reduce the threat. An environmental system management with a buffer zone on a soil with a good level of organic matter combined with the choice of pesticides that present less threat, is desirable.

Tools like PIRI will play a key role in the future in the assessment of pesticides risks on waters. CHEN *et al*.; [14] on analyzing a surface water mobility index (SWMI) based mainly on degradation half life and K_{oc} (also taken into account in PIRI) to the concentrations of pesticides in agricultural drainage watersheds found that there were statistically correlated.

Table V Insecticides ranking for ground water on considering different Scenarios

Pesticides	Scenario 1	Scenario 2	Scenario 3	Scenario 4	Scenario 5
endosulfan	Very low	Very low	Very low	Very low	Very low
esfenvalerate	Very low	Very low	Very low	Very low	Very low
chlorpyriphos	Very low	Very low	Very low	Very low	Very low
Lambda-cyhalothrin	Very low	Very low	Very low	Very low	Very low
cypermethrin	Very low	Very low	Very low	Very low	Very low
benfuracarb	Very low	Very low	Very low	Very low	Exceedingly. high
cyfluthrin	Very low	Very low	Very low	Very low	Very low
deltamethrin	Very low	Very low	Very low	Very low	Very low
Alpha-cypermethrin	Very low	Very low	Very low	Very low	Very low
profenofos	Very low	Very low	Very low	Very low	Very low
dimethoate	Very low	Very low	Very low	Very low	Very low
omethoate	Very low	Very low	Very low	Very low	Very low
methamidophos	Very low	Very low	Very low	Very low	Very low
pyriproxyfen	Very low	Very low	Very low	Very low	Very low

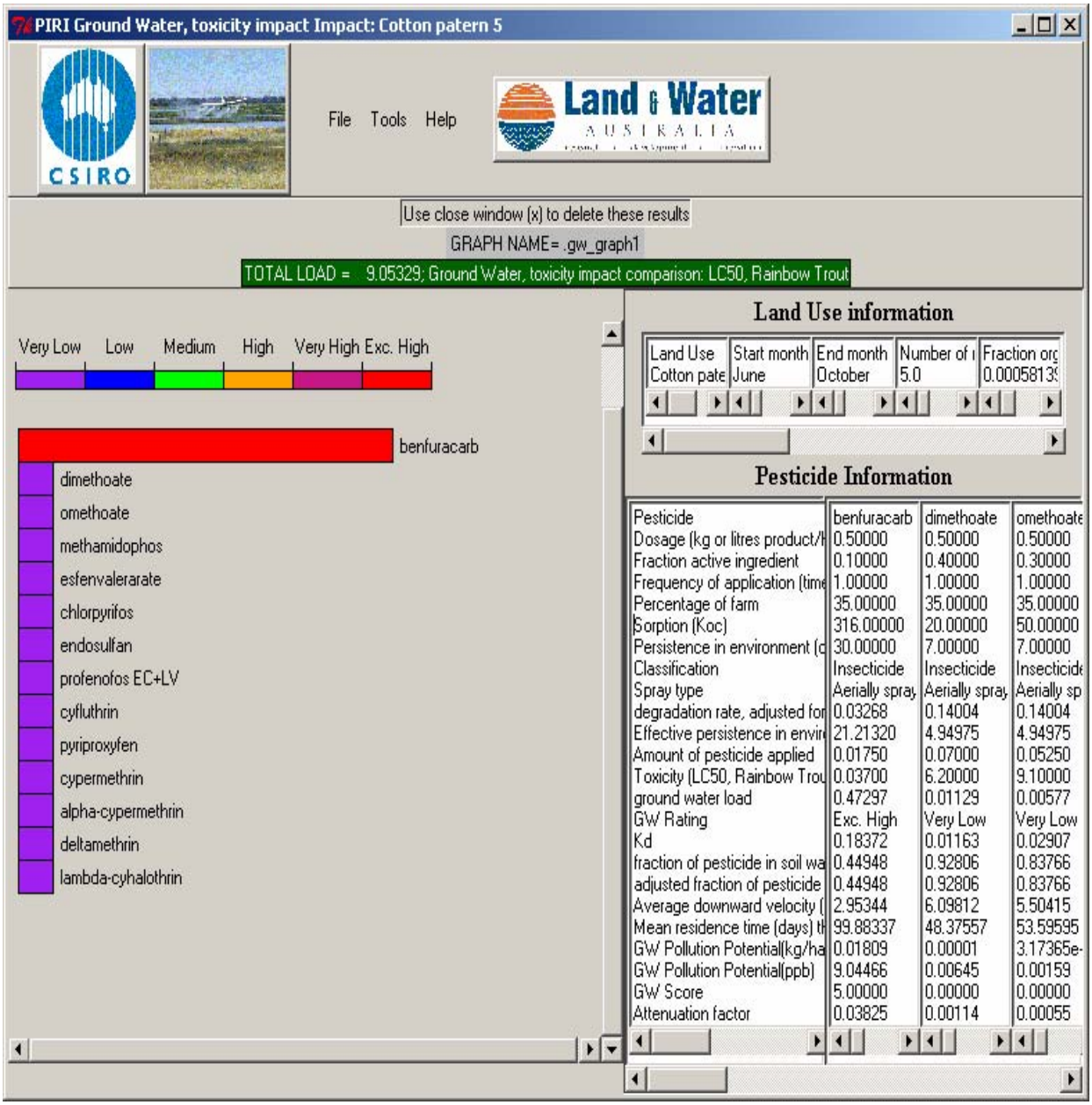

Figure 2 Insecticides ranked for ground water (scenario 5)

Conclusion

The overall trends related to the risks of using pesticides in Burkina Faso shows that for cotton production:

- the use of endosulfan as a foliar application for insecticides could lead to the greatest potential threat to the surface water .

- The other pesticides don't represent a large threat except with soils of low organic matter content and fields near the surface water;

It is noteworthy that these results are obtained in considering specific situations of land use. Other results with bad conditions of land use and bad Agricultural Practices could lead to severe impact of pesticides on the water resources.

In the context of Burkina Faso, water resources are very important. In the context of Burkina Faso, the surface water represents an important asset because it is drunk by humans and also by both domestic and wild animals. In addition fish from this water are consumed and sometimes the water is used for irrigation. Consequently, the protection of this natural resource is very important. In considering the major factors responsible for the threat such as: the soil organic matter content, the distance between the field and the water body, the width of the buffer zone, the number of days between the application and the rainfall, the three first factors might be monitored because they could be controlled. Another controlling factor is that the choice of pesticides can be modified by the growers.

In short, the threat of pesticides to natural water resources is evident in some extent. It must be alleviated and monitored. Up to now there is no Environmental Management System for cotton culture in Burkina Faso. This lack must be corrected. Our work sets up the basis of such upcoming programs based on relevant selections of pesticides, the setting up of appropriate buffer zones and the distance between the field and the water body.

This assessment of the risks related to the pesticides used in Burkina Faso is one of the firsts in the history of Burkina Faso and probably in many Sahelian countries. We hope that it will be regarded as a good step in the right direction. In anticipation, we thank all those Government, Companies, International Institutions, and Non Governmental Organizations for their awareness of the importance of conservation of natural water resources, who will help us to continue to examine and improve this work.

PIRI seems to be very adapted for the developing countries like Burkina Faso with poor resources and where the setting up and maintenance of .laboratories are very difficult. PIRI could be a handy tool for help in decision taking .

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APPENDIX A The software package PIRI

(Developed by Dr. R. Kookana, Dr. R. Correll and Mrs R. Miller, 2003)

- provides ratings for each pesticide's pollution potential to surface **and** ground water;
- assesses relative impacts of different land uses in a catchment;
- serves as an education tool and enhances awareness of the potential risk of pesticides;
- is user-friendly, being simple and easy to use;
- is scientifically sound and semi-quantitative;
- considers pesticide toxicity to fish, flea, algae and humans
- integrates pesticide properties (toxicity, persistence in the environment, sorption to soil), their use scenario and specific soil and site conditions (permeability, depth of water table and water input).
- utilises built-in data bases and requires minimum input parameters. Where possible, sensible default values are provided to assist the users.
- contains a data base which includes information on a large number of pesticides – their fate data (sorption, degradation), toxicity data (LC50 for fish, daphnia, algae), drinking water Health Advisory Levels, and recommended rates for pesticide use for selected land uses.
- has been compared with the results of pesticide residue monitoring in two intensive agricultural areas and found to be correct in more than 80% of cases.

COMITÉ PERMANENT INTER- ÉTATS DE LUTTE CONTRE LA SÉCHERESSE DANS LE SAHEL

PERMANENT INTERSTATES COMMITTEE FOR DROUGHT CONTROL IN THE SAHEL

INSTITUT DU SAHEL

Consultation Mission Report

Examination of pesticides for conversion from provisional sale authorization to registration

Sahelian Pesticide Committee (CSP)

Dr Adama M. TOÉ (Toxicologist - Ecotoxicologist)
CSP Expert

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We are most appreciative of the trust placed in us by CSP senior officials and hope that we have lived up to their expectations.

1. Introduction

At the extraordinary session of the CSP that was held from 19 to 30 December 2005 in Bamako, it was recommended that two CSP experts, namely Mr Macoumba M'BODJ and Mr Adama M. TOÉ , support the Institut du Sahel (INSAH) in enhancing the CSP work procedures for the "Study of Pesticides for Conversion from Provisional Sale Authorization (PSA) to Registration". This support was to be provided in the form of a consultation mission with the following specific objectives:

- To evaluate requirements and criteria for the conversion of 66 products from PSA to registration;
- To propose to the CSP products qualified for conversion without additional information;
- To propose products for which additional information was required and to determine the nature of such information;
- To propose a methodology for the future.

The mission was carried out from 17 to 23 July 2007 in Bamako by Mr Adama Toé in the absence of Mr Macoumba M'Bodj. This is a synthesis report on the work undertaken.

2. Methods of work

Identification of products having received two PSAs which expired before 2006;

Classification of products into 3 groups:
- Pesticides used in desert locust control (DLC);
- Products under toxicosurveillance;
- Other products.

Identification of the active substances concerned;

Identification of data needed for the evaluation of active substances (7.Annex):
- Name of active substances
- Evaluation of risks to humans
  - LD_{50} (mg/kg) (see Annex 7.2 for definition)
  - ADI (mg/kg/d)
  - ARfD (mg/kg/d)
  - AOEL (mg/kg/d)
- Evaluation of risks to non-target organisms
  - PNEC (µg/L)
- Evaluation of (physical) risks to the environment
  - K_{OC}
  - DT_{5O}

NB : see Annex 7.2 for meaning and definition of acronyms and abbreviations

- Classification
  - Consultation of databases on AGRITOX , EXTOXNET, EPA, PIP and other sites.
  - Analysis of toxicological and ecotoxicological profiles of active substances concerned;

- Use of decision grids;
- Information on registration status of individual active substances in other regions;
- Personal experience.

3. Work constraints and limits:

- Absence of Sahelian data;
- Contrasting and dispersed data;
- Frequency of binary, even tertiary, products for which there is no environmental data;
- Reliability of databases (possible errors, out-of-date);
- Absence of agreed decision grid;
- Very limited time available.

4. Results

4.1. Results of evaluation of pesticides used in desert locust control

4.1.1. Identification of main pesticides used and evaluation of their potential risks to humans and the environment

The pesticides used are mainly 18 formulations (**Table 1**) derived from 11 active substances (**Table 2**): 3 synthetic pyrethrinoids, 4 organophosphors and 1 phenylpyrazole (fipronil), 1 carbamate, 1 benzoylurea, 1 mycopesticide.

- **Evaluation of potential hazards to humans**

Examination of the toxicological profiles (DL_{50}) indicates that only the formulations based on chlorpyrifos-methyl and those based on phenitrothion at under 200 g/l belong to the non-hazardous U class under normal conditions of use. The other products are in classes III (slightly hazardous) and II (highly hazardous).

Fipronil carries serious health risks from prolonged exposure through ingestion.

- **Evaluation of potential hazards to the environment (except cyanophos)**

Risk for aquatic organisms (fish and arthropods):

Chlorpyrifos-ethyl and fipronil are high-risk for aquatic arthropods. Fipronil can cause long-term harm to the aquatic environment. The other products used are low-risk for fish in general.

Risk for terrestrial vertebrates:

No product seems to present a major hazard.

Risk for non-target terrestrial arthropods (wasps, natural predators, earth insects):

Fipronil, phenitrothion and chlorpyrifos-ethyl are high-risk.

Risk of persistence in the soil (by DT_{50} classification):

None of the products belongs to the “very slightly degradable” class. They do not therefore include any persistent products.

Risk of mobility and contamination of surface waters through runoff (K_{OC} index)

Mobility of the products used is very low, reducing the risk of contamination of surface waters from runoff. On the other hand, use of the carbosulfan-based product can incur high risk of pollution of groundwaters. The main product of degradation of carbosulfan is carbofuran. It is worth noting that in its current decision on eligibility for registration, the EPA prescribes the immediate cancellation of all uses of carbofuran, except for 6 minor crops that account for 2% of sales.

4.1.2. Recommendation for the registration of pesticides used in desert locust control

Considering that 6 pesticides are already registered by the CSP for desert locust control, including 5 based on chlorpyrifos-methyl (class II) and 1 based on diflubenzuron (class II);

Taking into account the wide availability in the Sahel countries of data on the effects of desert locust control on health and the environment:

Considering the findings of study of the toxicological and ecotoxicological profiles;

Considering the registration status of these products in other regions (European Union, USA);

With the reservation that the outcome of the 2004 assessment of the impact of desert locust control in the countries of the Sahel does not reveal serious impacts of these products on health and the environment;

We recommend the conversion to registration of 14 pesticides (**Table 1**) with the following restrictions:

- That farmer groups only use products in the U class;
- That specialized operators only use products in classes III and U;
- That pilots only use those in classes III , II and U.

In addition, in order to reduce risk, preference should be given to the least concentrated formulations. All these products should be used in accordance with FAO guidelines on desert locust control, in particular the observance of buffer strips during ground and aerial application.

Because of its inadequate database, the product based on cyanophos requires supplementary information on its use in other regions. Before it can be used in the Sahel, the manufacturing company should provide the results of environmental impact studies. We therefore keep it under study.

We are against the registration of the product based on fipronil because of the above-mentioned toxicological and ecotoxicological risks.

Table 1 : Pesticides used in desert locust control and opinion for registration

Commercial product	WHO Class	Company	Active substance(s)	Number	Opinion
ALSYSTIN 050 UL	III	Bayer Crop Science	triflumuron (50 g/l)	0109/I/12-00/APV-SAHEL 0109/I/12-03/APV-SAHEL	Favourable
ADONIS 4 UL	III	Rhône Poulenc	fipronil (4 g/l)	0065/I/11-99/APV-SAHEL 0065/I/06-02/APV-SAHEL	Unfavourable
CONFIDOR 010 UL	III	Bayer	imidacloprid (10 g/l)	0165/I/11-01/APV-SAHEL	Favourable for renewal PSA
CYANOX L-50	II	Sumitomo Corporation	cyanophos (500 g/l)	0107/I/12-00/APV-SAHEL 0107/I/12-03/APV-SAHEL	RS
MARSHAL 2% DP	III	FMC Europe	carbosulfan (20 g/kg)	0047/I/06-99/APV-SAHEL 0047/I/06-02/APV-SAHEL	Unfavourable
CYHALON 4 ULV	II	Syngenta	cyhalothrine (40 g/l)	0175/I/06-02/APV-SAHEL	Favourable for renewal PSA
GREEN MUSCLE	III	Calliope	metarhizium flavovirid (5.10^{10} spores/g)	0152/I/06-01/APV-SAHEL	Favourable for renewal PSA
OFUNACK 40 EC	II	Africa Agro Service	pyridaphenthion (400 g/l)	0092/I/05-00/APV-SAHEL	Favourable for renewal PSA
OFUNACK 25 ULV	II	Africa Agro Service	pyridaphenthion (250 g/l)	0093/I/05-00/APV-SAHEL	Favourable for renewal PSA
RELDAN 50 EC	U	Dow AgroSciences	chlorpyrifos-methyl (500 g/l)	0016/I/06-95/APV-SAHEL 0016/I/11-01/APV-SAHEL	Favourable
RELDAN 500 ULV	U	Dow AgroSciences	chlorpyrifos-methyl (500 g/l)	0017/I/06/95/APV-SAHEL 0017/I/11-01/APV-SAHEL	Favourable
RELDAN 170 ULV	U	Dow AgroSciences	chlorpyrifos-methyl (170 g/l)	0018/I/06-95/APV-SAHEL 0018/I/11-01/APV-SAHEL	Favourable
SUMICOMBI 30 EC	II	Sumitomo Corporation	phenitrothion (250 g/l) phenvalerate (50 g/l)	0099/I/12-00/APV-SAHEL	Favourable

				0099/I/12-03/APV-SAHEL	
SUMICOMBI-ALPHA 25 ULV	II	Sumitomo Corporation	phenitrothion (245 g/l) esphenvalerate (5 g/l)	0100/I/12-00/APV-SAHEL 0100/I/12-03/APV-SAHEL	Favourable
SUMITHION 3 D	U	Sumitomo Corporation	phenitrothion (30 g/kg)	0101/I/12-00/APV-SAHEL 0101/I/12-03/APV-SAHEL	Favourable
SUMITHION 5 D	U	Sumitomo Corporation	phenitrothion (50 g/kg)	0102/I/12-00/APV-SAHEL 0102/I/12-03/APV-SAHEL	Favourable
SUMITHION 50 EC	II	Sumitomo Corporation	phenitrothion (500 g/l)	0103/I/12-00/APV-SAHEL 0103/I/12-03/APV-SAHEL	Favourable
SUMITHION L-20	U	Sumitomo Corporation	phenitrothion (200 g/l)	0104/I/12-00/APV-SAHEL 0104/I/12-03/APV-SAHEL	Favourable
SUMITHION L-50	II	Sumitomo Corporation	phenitrothion (500 g/l)	0105/I/12-00/APV-SAHEL 0105/I/12-03/APV-SAHEL	Favourable
SUMITHION L-100	II	Sumitomo Corporation	phenitrothion (1000 g/l)	0106/I/12-00/APV-SAHEL 0106/I/12-03/APV-SAHEL	Favourable
TRACKER 16,5ULV	III	Du Pont de Nemours	tralomethrin (66 g/l)	0022/I/12-95/APV-SAHEL 0022/I/05-00/APV-SAHEL	Favourable
UNDEN 2 DP	III	Bayer CropScience	propoxur (20 g/kg)	0108/I/12-00/APV-SAHEL 0108/I/12-03/APV-SAHEL	Favourable

Table 2. Active substances in desert locust control products

Active substance	EU status	USA status	Database situation	Opinion on registration
fipronil	Authorization in process	Authorized	XXX	no
triflumuron	Authorization in process	-	-	yes
metarhizium flavovirid	-	-	-	yes
phenitrothion	-	Authorized	XXX	yes
propoxur	Expired	Authorized	XXX	yes
cyanophos	-	-	-	RS
phenvalerate			X	yes
esphenvalerate	Authorized	Authorized	XXX	yes
tralomethrin	-	-	-	
carbosulfan	Authorization in process		XXX	no
chlorpyriphos-methyl			XXX	yes

EU : European Union

X : little available data
XX : moderate available data
XXX : abundant available data

4.2. Results of evaluation of pesticides under toxicosurveillance

The pesticides under toxicosurveillance are all products of toxicological class Ib used against cotton pests. There are 14 commercial products (**Table 3**) derived from 9 active substances (**Table 4**). Eight are based on endosulfan and eight on other active substances (**Table 2**). Nine of the 14 products have already received 2 PSAs while 3 present serious problems and cause concern (endosulfan, methamidophos and monocrotophos).

4.2.1. Endosulfan

Endosulfan is an organochloride insecticide with two isomers: α and ß which metabolize into endosulfan sulphate and endosulfan diol. Endosulfan sulphate, the main product of degradation is more toxic and persistent than endosulfan.

The neurotoxic effects of endosulfan on humans and animals are well documented. Exposure can cause liver and kidney toxicity, haematological effects and alterations to the immunity system and reproductive organs.

Endosulfan is in the environment, more specifically in air, soil and sediments. Its persistence in the environment is as follows:

- The DT_{50} of endosulfan α is 60 days
- La DT_{50} of endosulfan ß is 900 days

Because of its potential displacement over long distances, its persistence in the environment, its bioaccumulation in various aquatic organisms and its ecotoxicity, there is agreement that endosulfan and its metabolite endosulfan sulphate meet the criteria for inclusion in the list of Persistent Organic Pollutants (POP).

As regards the Rotterdam Convention, endosulfan is one of those products for which a Decision Guidance Document (DGD) is being prepared.

As regards the European Union, endosulfan is banned following its examination for inclusion in Annex I (positive list) of Directive 91/414/EEC, in application of community decision 2005/864/EC of 2 December 2005.

This refusal of the European Union to include endosulfan in its positive list is due to the fact that it does not meet minimum safety requirements, particularly its impact on the environment and its ecotoxicological profile. It was authorized for use in 7 countries of the Union. That authorization should have been withdrawn from the 1 February 2006 (EFSA Journal (2005) 234,1-31.

In France, endosulfan is not authorized in the composition of formulations granted market sale authorization. The determination published in the Official Gazette of 22 February 2006 withdraws market sale authorizations of phytopharmaceutical products containing endosulfan for all agricultural and non-agricultural uses, with a time limit set on stock throughput:

- until 31 December 2006 for distribution,
- until 30 May 2007 for use.

In the USA, agricultural uses and MRLs of certain usages are cancelled.

For the countries of the CILSS, endosulfan is used for the cotton crop at a dose of 500 to 700 g/ha following a major outbreak of *Helicoverpa armigera* in 1996 and its resistance to pyrethrinoids. For the cotton producing countries of the CILSS, large quantities of this hazardous product have been heavily used without respecting good agricultural practices, resulting in serious risks to human health and the environment for some ten years. In a classification of pesticides according to their impact on surface waters in Burkina Faso, of all the pesticides applied as foliar spray to the cotton crop, endosulfan is the only one classified as having an excessively high risk of contamination of surface waters (TOE *et al,* 2003). This threat to surface waters from endosulfan identified by the Pesticide Impact Rating Index (PIRI) has been confirmed by the presence of endosulfan residues after GPC-ECD analysis of water samples taken from the area in which this product was used (TOE *et al,* 2004).

Because of its very high toxicity (class Ib) and the serious danger it poses for human and animal health, the environment and non-target organisms, and in view of the provisions of international conventions on organochlorides, endosulfan cannot remain authorized in CILSS countries with particularly fragile ecological conditions.

Use of this product is no longer justified in the CILSS countries, because there are now many other products capable of effectively controlling *H. armigera*. In application of article 13.5(iii) of the common regulation of the CILSS Member States on the registration of pesticides, we

recommend that no current PSA be renewed for endosulfan-based products and that no registration be granted. We also strongly recommend that a time limit be set on stock throughput, taking into consideration the period of cotton pesticide use and the lead time from ordering by the cotton producing companies:

- until 30 October 2007 for distribution,
- until 30 October 2008 for utilization.

We also recommend that the CILSS launches an information campaign on behavioural change aimed at all operators using endosulfan.

4.2.2. Methamidophos and monocrotophos

Methamidophos (concentration above 600 g/ha) and monocrotophos are included in the PIC list (Annexe III).

Because of its toxicity, monocrotophos is banned in the European Union countries and in the USA. Methamidophos is not authorized in the European Union countries. For the Rotterdam Convention, two countries in two different regions (Nigeria and Bulgaria) have already provided the information needed for a revision of the status of this molecule in the PIC list. Our own research revealed that all incidences of toxicity in cotton production in Burkina Faso in 1996-1997 were due to methamidophos-based products (TOE *et al*, 2000; TOE *et al*, 2002).
In further application of article 13.5, we propose withdrawing current PSAs for all products based on methamidophos and monocrotophos, and propose setting a time limit for stock throughput, as for endosulfan.

4.2.3. Other class Ib products.

Products based on carbosulfan

We are strongly against the registration of these products because of associated risks of groundwater pollution.

Conquest plus 388 EC (ternary)

Insecticide/herbicide ternary products used on a large scale are generally very broad spectrum, making it difficult to avoid non-target organisms. In addition, their physico-chemical qualities deteriorate rapidly in storage and use. We are strongly against their registration.

Dursban B 18/150 EC and B 18/200 (based on cyfluthrin and chlorpyrifos).

Because of their toxicity, we suggest that these products should not be registered once their PSAs expire.

4.2.4. Conclusion for class Ib products

These products are used by small farmers who are poorly trained in the safe use of pesticides. They do not observe recommended hygienic practices and do not wear appropriate protective equipment. We therefore propose that class Ib products meant for use by small farmers no longer be authorized by the CSP because of the restrictions placed on their use which cannot be observed by poorly trained and often illiterate small operators. In the case of cotton, there is a wide range of class II, III and IV products that are equally effective. There is absolutely no justification in using class Ib products. Similarly, we propose that ternary products should no longer be authorized, given their very broad spectrum of activity in Sahel countries with fragile ecological conditions.

Table 3: Pesticides under toxicosurveillance and opinion for registration

Commercial product	WHO Class	Company	Active substance(s)	Number	Opinion on registration
CAÏMAN 500 EC	Ib	STEPC	endosulfan (500 g/l)	0214/I,A/06-03/APV-SAHEL	Unfavourable
CONQUEST PLUS 388 EC	Ib	Aventis	acetamiprid (16g/l), cypermethrin (72 g/l) and triazophos (300 g/l)	0086/I/05-00/APV-SAHEL 0086/I/05-03/APV-SAHEL	Unfavourable
CYPERFOS 336 EC	Ib	Senchim AG	cypermethrin (36 g/l) and methamidophos (300 g/l)	0217/I,A/06-03/APV-SAHEL	Unfavourable
CYTOFOS 286 EC	Ib	Senchim AG	cypermethrine (36 g/l) monocrotophos (250 g/l)	0218/I/06-03/APV-SAHEL	Unfavourable
DURSBAN - B 18/150 EC	Ib	Dow AgroSciences	cyfluthrin (18 g/l) and chlorpyrifos (150 g/l)	0128/I/06-01/APV-SAHEL 0128/I/06-04/APV-SAHEL	Unfavourable
DURSBAN - B 18/200 EC	Ib	Dow AgroSciences	cyfluthrin (18 g/l) and chlorpyrifos (200 g/l)	0129/I/06-01/APV-SAHEL 0129/I/06-04/APV-SAHEL	Unfavourable
ENDOCOTON 350 EC	Ib	Hydrochem CI	endosulfan (350 g/l)	0119/I/12-00/APV-SAHEL 0119/I/12-03/APV-SAHEL	Unfavourable
ENDOCOTON 500 EC	Ib	Hydrochem CI	endosulfan (500 g/l)	0120/I/12-00/APV-SAHEL 0120/I/12-03/APV-SAHEL	Unfavourable
MARSHAL 25 EC	Ib	FMC Europe	carbosulfan (250 g/l)	0046/I/06-99/APV-SAHEL 0046/I/06-02/APV-SAHEL	Unfavourable
PHASER 350 EC	Ib	Bayer CropScience	endosulfan (350 g/l)	0082/I/05-00/APV-SAHEL 0082/I/05-03/APV-SAHEL	Unfavourable
PHASER 500 EC	Ib	Bayer CropScience	endosulfan (500 g/l)	0113/I/12-00/APV-SAHEL 0113/I/12-03/APV-SAHEL	Unfavourable
ROCKY 500 EC	Ib	Calliope	endosulfan (500 g/l)	0200/I/06-02/APV-SAHEL	Unfavourable
ROCKY 500 EC	Ib	Calliope	endosulfan (500 g/l)	0200/In,Ac/06-02/APV-SAHEL 0200/In,Ac/06-05/APV-SAHEL	Unfavourable
ROCKY 330 CS	Ib	Calliope	endosulfan (330 g/l)	0244/In,Ac/07-05/APV-SAHEL	Unfavourable

Table 4. Active substance of the pesticides under toxicosurveillance

Active substance	European Union status	USA status	Database situation	Opinion on registration
triazophos	expired	-	-	yes and no
endosulfan	expired	authorized	XXX	no
methamidophos	-	authorized	XXX	no
monocrotophos	banned	Banned 01 91	XXX	no
carbosulfan	authorization in process		XXX	no
acetamiprid	-	-	XXX	yes
chlorpyriphos-ethyl	-	authorized	XXX	yes
cyfluthrin	-		XXX	yes
cypermethrin			XXX	yes

4.3. Results of evaluation of other pesticides

Products for which there would not appear to be any obvious objection to registration would be those based on the following active substances:

cyfluthrin
indoxacarb
ioxynil
acetamiprid
zeta-cypermethrin
buprofezin
cypermethrin
bensulfuron-methyl
profenofos
permethrin
malathion
oxadiargyl
fluometuron
prometryn

Products to remain under study:

pyrimiphos-methyl
triazophos
phenthoate
isoprothiolane

We have kept these products under study at the present stage of our investigations, as we do not have enough information from the databases consulted and do not know their EU or USA status.

We recommend that the CSP continue more in-depth investigations into these active substances.

Product to be banned: paraquat

Paraquat is a highly toxic non-selective herbicide when ingested. Any paraquat-based formulation is obliged to contain a stenching agent and an emetic agent. This product has also proved to be mutagenic in tests with microorganisms. Paraquat is among those pesticides that alter immunitary functions and significantly reduce the resistance of organisms to infection (immunosuppressants). They alter organism defences against microbial or toxic aggression. Paraquat and diquat in particular reduce the formation of antibodies and disturb white blood cell phagocytosis. Paraquat is very persistent in the environment with half-life times in excess of 1000 days and in certain areas 13 years. Under such conditions, the risks are significant to both the environment and non-target organisms.

Because of these toxicological and ecotoxicological risks, tight restrictions have been placed on use of this product. We therefore recommend that this product should not be registered for use by small farmers in CILSS countries with fragile ecological conditions.

Table 5 : Other pesticides and opinion for registration

Commercial product	WHO Class	Company	Active substance(s)	Number	Opinion on registration
ACTALM SUPER	U	ALM International	pyrimiphos-methyl (17 g/l) and cyfluthrine (3 g/l)	0097/I/05-00/APV-SAHEL 0097/I/05-03/APV-SAHEL	RS
ACTRIL DS	U	Bayer CropScience	ioxynil (100 g/l) and 2,4-D (577 g/l)	0067/H/11-99/APV-SAHEL 0067/H/11-02/APV-SAHEL	Favourable
APPLAUD 40 SC	III	Nihon Nohyaku	buprofezin (400 g/l)	0110/I/12-00/APV-SAHEL 0110/I/12-03/APV-SAHEL	Favourable
AVAUNT 150 SC	III	Asteria	indoxacarb (150 g/l)	0039/I/06-99/APV-SAHEL 0039/I/06-02/APV-SAHEL	Favourable
CONQUEST 88 EC	II	Bayer CropScience	acetamiprid (16 g/l) and cypermethrin (72 g/l)	0114/I/12-00/APV-SAHEL 0114/I/12-03/APV-SAHEL	Favourable
COTOGARD 500 SC	III	Agan Chemical	fluometuron (250 g/l) and prometryn (250 g/l)	0089/H/05-00/APV-SAHEL 0089/H/05-03/APV-SAHEL	Favourable
CYPERCAL 50 EC	III	Calliope	cypermethrin (50 g/l)	0037/I/11-98-APV-SAHEL 0037/I/11-02/APV-SAHEL	Favourable
CYPERCAL P 186 EC	II	Calliope	cypermethrin (36 g/l) and profenofos (150 g/l)	0124/I,A/12-00/APV-SAHEL 0124/I,A/12-03/APV-SAHEL	Favourable
CYPERCAL P 230 EC	II	Calliope	cypermethrin (30 g/l) and profenofos (200 g/l)	0125/I,A/12-00/APV-SAHEL 0125/I,A/12-03/APV-SAHEL	Favourable
CYPERCAL P 286 EC	II	Calliope	cypermethrin (36 g/l) and profenofos (200 g/l)	0126/In,Ac/12-00/APV-SAHEL 0126/In,Ac/12-03/APV-SAHEL	Favourable
ELSAN 50 EC	II	Tomen	phenthoate (500 g/l)	0052/I/06-99/APV-SAHEL 0052/I/06-02/APV-SAHEL	RS
FUJI-ONE 40 EC	III	Nihon Nohyako	isoprothiolane (400 g/l)	0034/F/11-98/APV-SAHEL	RS

				0034/F/06-02/APV-SAHEL	
FURY P 162 EC	II	FMC	zeta-cypermethrin (12 g/l) and profenfos (150 g/l)	0117/I,A/12-00/APV-SAHEL 0117/I,A/12-03/APV-SAHEL	Favourable
GRAMOXONE SUPER	II	Syngenta	paraquat (200 g/l)	0096/H/05-00/APV-SAHEL 0096/H/05-03/APV-SAHEL	Unfavourable
KALACH 360 SL	III	Calliope	glyphosate (360 g/l)	0049/H/06-99/APV-SAHEL 0049/H/06-02/APV-SAHEL	Favourable
LONDAX 60 DF	III	Dupont de Nemours	bensulfuron-methyl (600 g/l)	0053/H/06-99/APV-SAHEL 0053/I/06-02/APV-SAHEL	Favourable
PERCAL M DP	III	Calliope	permethrin (4 g/kg) and malathion (16 g/kg)	0050/I/06-99/APV-SAHEL 0050/I/06-02/APV-SAHEL	Favourable
TOPSTAR 400 SC	III	Bayer CropScience	oxadiargyl (400 g/l)	0084/H/05-00/APV-SAHEL 0084/H/05-03/APV-SAHEL	Favourable
TRIAZOPHOS HOSTATHION 40 EC	II	Bayer CropScience	triazophos (420 g/l)	0112/I/12-00/APV-SAHEL 0112/I/12-03/APV-SAHEL	RS

RS : Remain under study

Table 6: Active substances of other pesticides

Active Substance	European Union Status	USA Status
pyrimiphos-methyl (17 g/l) et l)	-	-
cyfluthrin (3 g/	-	-
ioxynil (100 g/l) et	-	-
2,4-D	-	-
buprofezine (400 g/l)	-	-
indoxacarb	authorized	authorized
acetamiprid (16 g/l)	-	-
cypermethrin		-
fluometuron		
prometryn	-	-
profenofos (150 g/l) (3)	expired	-
phenthoate (500 g/l)	expired	-
isoprothiolane (400 g/l)	expired	-
zeta-cypermethrin (12 g/l)	-	-
paraquat (200 g/l)	authorized	authorized
glyphosate (360 g/l)	-	authorized
bensulfuron-methyl (600 g/l)	-	-
permethrin (4 g/kg)	-	-
malathion (16 g/kg)	authorization in process	authorized
oxadiargyl (400 g/l)	authorized	-
triazophos (420 g/l)	expired	-

5. Conclusions and outlook

Our determination based on expert analysis and available data is as follows:

- a favourable opinion for the registration of all pesticides used in desert locust control that have already been granted 2 PSAs, with the exception of fipronil and cyanophos. Fipronil should be banned and cyanophos should remain under study;

- a very unfavourable opinion for the registration of all pesticides under toxicosurveillance (pesticides in toxicological class 1b) with a time limit set on stock throughput;

- a favourable opinion for the registration of all the other pesticides that do not belong to the two above classes and all products except those based on: paraquat, pyrimiphos-methyl, triazophos, phenthoate and isoprothiolane. We strongly recommend that paraquat be banned and that the other four products remain under study.

We have constantly borne in mind that risks associated with phytopharmaceutical products can only be considered in relation to the usage of those products. A decision on registration should be taken on the basis of individual usage and not only individual product. We therefore strongly recommend that any decision on conversion from PSA to registration should be made on the basis of more in-depth examination of each case with the involvement of stakeholders (distributors, users, certification services, civil society...). Supplementary information should be provided for all cases with details on:

- the use and distribution of the products (companies) ;
- the effectiveness and phytotoxicity of the products (users) ;
- the observed impacts on health and the environment (……).

For conversion of binary products from PSA to registration, we must insist that companies provide data on the effects of those binary products on the environment and on non-target organisms.

Regarding future work of the CSP in general and Sub-Committee II (Toxicology – Ecotoxicology) in particular, we reiterate all the suggestions and recommendations we made in our mission report to the INRA Joint Research Unit in Versailles last December.

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Databases consulted: CSP, AGRITOX, Pesticide Manual, EXTOXNET, EPA., PIP…

7. Annex

7.1. Essential data for evaluation of active substances:

Substance	ADI (mg/kg/d)	ARfD (mg/kg/d)	AOEL (mg/kg/d)	PNEC (µg/L)	Classification
2,4-D	0.05	not applicable	0.15	58	N Xn R22 R37 R41 R43 R52/53
acetamiprid	0.07	0.1	0.124	0.5	Xn R22 R52/53 S2 S46 S61
bensulfuron-methyl	0.2				N Xi R43 R51/53
bifenthrin	0.015	0.074	0.0125	0.0012	N T R20 R25 R40 R43 R50/53 S36/37 S45 S60 S61
buprofezin	0.01				EC
carbofuran	0.001	0.001	0.001		N T+ R26/28 R50/53
carbosulfan	0.01	0.01	0.02		N T R23/25 R43 R50/53 S1/2 S36/37 S45 S60 S61
chlorpyriphos-ethyl	0.01	0.1	0.01	0.1	N T R25 R50/53 S1/2 S45 S60 S61
chlorpyriphos-methyl	0.01	0.1	0.01		N Xi R43 R50/53 S2 S36/37 S60 S61
cyfluthrin	0.003	0.02	0.02	0.0068	N T+ R23 R28 R50/53
cypermethrin	0.05	0.2	0.06	0.001	N Xn R20/22 R37 R50/53 S2 S24 S36/37/39 S60 S61
cypermethrin high cis					N Xn R22 R37/38 R43 R50/53 S2 S36/37/39 S60 S61
deltamethrin	0.01	0.01	0.0075	0.0032	N T R23/25 R50/53 S1/2 S24 S28 S36/37/39 S38 S45 S60 S61
diflubenzuron	0.02				EC
esphenvalerate	0.02	0.05	0.018	0.08	N T R23 R25 R43 R50/53 S1/2 S24 S36/37/39 S45 S60 S61
fenitrothion	0.005	0.013	0.013		N Xn R22 R50/53
fipronil	0.0002	0.009	0.0035	0.00077	N T R23/24/25 R48/25 R50/53 S2 S36/37 S45 S60 S61
glyphosate	0.3	not applicable	0.2	60	N Xi R41 R51/53 S2 S26 S39 S61

indoxacarb	0.006	0.125	0.004		Xn R22 R43 R50
ioxynil	0.005	0.04	0.01	2.7	N T R21 R23/25 R36 R48/22 R50/53 R63 S1/2 S36/37 S45 S60 S61 S63
lambda cyhalothrin	0.005	0.0075	0.0025	0.00016	N T+ R21 R25 R26 R50/53
malathion	0.03	0.3	0.03	0.5	N Xn R22 R50/53 S2 S24 S60 S61
methamidophos	0.001	0.003	0.001		N T+ R24 R26/28 R50 S1/2 S28 S36/37 S60 S61
oxadiargyl	0.008	not applicable	0.006	0.23	N Xn R48/22 R50/53 R63 S2 S36/37 S46 S60 S61
prometryne					EC
spinosad	0.024	not applicable	0.024 0.012	0.17	N Xn R48/22 R50/53 S2 S46 S60 S61
triflumuron	0.005				Xn R48/22
zetacypermethrin	0.02		0.05	2.6e-05	N T R23 R25 R43 R50/53
zirame	0.006	0.08	0.015	18.9	N T+ R22 R26 R37 R41 R43 R48/22 R50/53 S1/2 S22 S26 S28 S36/37/39 S45 S60 S61
zoxamide	0.5	not applicable	0.3	0.348	N Xi R43 R50/53

7.2. Acronyms, abbreviations and definition of essential data for toxicological and ecotoxicological evaluation of active substances (see Chapter 2. Methods of work)

AOEL: Acceptable Operator Exposure Level
This is the maximum quantity of active substance to which operators can be exposed daily without harmful effects on their health.

ARfd: Acute Reference Dose
This is the maximum quantity of active substance that can be ingested by consumers during a short period (i.e. during a meal or a day, in food or water) without harm to their health.

ADI: *Acceptable Daily Intake*
This is the quantity of the substance that can be ingested daily by consumers, throughout their lifetime, without effect on their health.

DL_{50} : Lethal Dose $_{50}$ (fatal) of active substance for 50 percent of experimental animals after a single administration of the active substance.

DT_{50} : Dissipation time (Half-life)
This is the time needed for the degradation (in the laboratory) or the dissipation (in the field) of 50 percent of the initial quantity of the active substance in the soil.

Koc: Adsorption coefficients
This characterizes the mobility of an active substance and indicates the risks of contamination of surface waters.

PNEC: Predicted No Effect Concentration
This is the concentration below which exposure is not expected to cause an effect on aquatic organisms.

Australian Pesticides & Veterinary Medicines Authority

The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels.

FINAL REVIEW REPORT AND REGULATORY DECISION

Review Series 2

June 2005

Australian Pesticides &
Veterinary Medicines Authority

Canberra
Australia

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This final review report for the active constituent Endosulfan, products containing Endosulfan and associated labels is published by the Australian Pesticides and Veterinary Medicines Authority. For further information about this review or the Pesticides Review Program, contact:

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FOREWORD

The APVMA is an independent statutory authority with responsibility for the regulation of agricultural and veterinary chemicals in Australia. Its statutory powers are provided in the *Agricultural and Veterinary Chemicals Code Act, 1994* (Agvet Codes).

The APVMA can reconsider the approval of active constituents, the registration of chemical products or the approval of labels for containers of chemical products at any time. This is specified in Part 2, Division 4 of the Agvet Codes.

The basis for the reconsideration is whether the APVMA is satisfied that continued use of the active constituent endosulfan and products containing endosulfan in accordance with the instructions for their use:

- would not be an undue hazard to the safety of people exposed to it during its handling; and/or
- would not be likely to have an effect that is harmful to human beings; and /or
- would not be likely have an unintended effect that is harmful to animals, plants or things or to the environment; and/or
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

A reconsideration may be initiated when new research or evidence has raised concerns about the use or safety of a particular chemical, a product or its label.

The process for reconsideration includes a call for information from a variety of sources, a review of that information and, following public consultation, a decision about the future use of the chemical or product.

In undertaking reviews, the APVMA works in close cooperation with advisory agencies including the Department of Health and Ageing, the Department of the Environment and Heritage, the National Occupational Health and Safety Commission, and State Departments of Agriculture as well as other expert advisors, as appropriate.

The APVMA has a policy of encouraging openness and transparency in its activities and community involvement in decision-making. The publication of review reports is a part of that process.

The APVMA also makes these reports available to the regulatory agencies of other countries as part of bilateral agreements. Under this program it is proposed that countries receiving these reports will not utilise them for registration purposes unless they are also provided with the raw data from the relevant applicant.

This document is *'The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels'* and relates to all products containing endosulfan. The review's findings and regulatory decision are based on information collected from a variety of sources. The information and technical data required by the APVMA to review the safety of both new and existing chemical products must be derived according to accepted scientific principles, as must the methods of assessment undertaken.

The final review report and regulatory decision containing the APVMA assessments (Volume I, June 2005) and the technical reports from its advisory agencies (Volume II) are available from the APVMA website: http://www.apvma.gov.au/chemrev/chemrev.shtml.

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GLOSSARY OF TERMS AND ABBREVIATIONS

AAAA	Australian Aerial Agricultural Association
ACAHS	Australian Centre for Agricultural Health & Safety
ADI	Acceptable Daily Intake
a.i.	Active Ingredient
ai/100L	active ingredient per 100 Litres
aPAD	Acute Population Adjusted Dose
ARfD	Acute Reference Dose
ATV	All Terrain Vehicles
BCF	Bioconcentration Factor
bw	Body weight
CAS	Chemical Abstracts Service
CNS	Central Nervous System
CP	Pressure control nozzles
cPAD	Chronic Population Adjusted Dose
C-PAS	Centre for Pesticide Application Safety
CRDC	Cotton Research & Development Corporation
CRP	Chemical Review Program
CXL	Codex Maximum Residue Level
d	Days
DFR	Dislodgeable Foliar Residue
EC	Emulsifiable concentrate
ECRP	Existing Chemical Review Program (APVMA)
EPA	US Environmental Protection Agency
ER	Oestrogen Receptor
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
FQPA	Food Quality Protection Act
g	Gram
g ai/ha	grams of active ingredient per hectare
GAP	Good Agricultural Practice
HPA	Hypothalamic-pituitary-adrenal
HPG	Hypothalamic-pituitary-gonadal
HPT	Hypothalamic-pituitary-thyroid
HRs	Highest Residues
IPM	Integrated Pest Management
kg	Kilogram
L	Litre
LOAEL	Lowest Observed Adverse Effect Level
LOD	Limit of Detection
LOEL	Lowest Observable Effect Level
MFL	Maximum Feed Level
mg	Milligram
mg/kg	milligrams per kilogram
mL	Millilitre
M/L	Mixing/loading
M/L/A/C	Mixing/loading/application/cleaning

MOE	Margins of Exposure
MRL	Maximum Residue Limits
NEDI	National Estimated Dietary Intake
NESTI	National Estimated Short Term Intake
NOAEL	No Observed Adverse Effect Level
NOEC	No Observable Effect Concentration
NOEL	No Observable Effect Level
NOHSC	National Occupational Health & Safety commission
OCS	Office of Chemical Safety
OHS	Occupational Health and Safety
OP	Organophosphorus compound
OPP	EPA Office of Pesticide Programs
OPPTS	EPA Office of Prevention, Pesticides and Toxic Substances
PAD	Population Adjusted Dose
PADI	Provisional Acceptable Daily Intake
PF	Processing Factor
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	parts per million
PVC	Polyvinyl chloride
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RLEM	Red Legged Earth Mite
SHBG	Sex hormone–binding globulin
STMRs	Supervised Trial Median Residues
SUSDP	Standards for the Uniform Scheduling of Drugs and Poisons
TC	Transfer Coefficient
TGA	Therapeutic Goods Administration
TGAC	Technical Grade Active Constituent
ULV	Ultra-low Volume
US EPA	United States Environment Protection Authority
WHP	With Holding Period

EXECUTIVE SUMMARY

Introduction

Endosulfan is a broad-spectrum insecticide/acaricide, which has been registered in Australia for over 35 years. It is used widely for the control of a large variety of insects and mites in horticultural and agricultural crops, including cotton, cereal, oilseeds, fruit, vegetables and other crops. Endosulfan products are not registered for home garden use.

There are five product registrations for endosulfan, all of which are emulsifiable concentrates. All of these product registrations are currently under suspension (since 2002), with new instructions issued for use under specified conditions.

Alternative products are available for all use patterns, although endosulfan has a number of important advantages in that it is inexpensive, soft on beneficial insects, and provides a different chemistry useful in resistance management. It is expected that increasing use of genetically modified cotton will reduce reliance on pesticides such as endosulfan.

Previous Reconsideration Action

In November 1995, the APVMA announced its decision to reconsider approvals and registrations associated with endosulfan. The review was initiated because of concerns regarding possible health and environmental effects, residues in commodities and possible trade implications.

An interim report of this review was released in 1998 and recommended a number of changes to the registered uses for endosulfan. Amongst other things, the interim report required additional Occupational Health & Safety (OH&S) and residues data to be provided, and set targets for reduction in endosulfan levels in surface waters. Subsequently, the endocrine disruption potential for endosulfan was also reassessed. This Final Review Report and Regulatory Decision, *The reconsideration of approval of the active constituent Endosulfan, registrations of products containing Endosulfan and their associated labels*, June 2005, considers the assessment of this additional information.

During the period 1998 to 2001, the APVMA implemented a range of changes to the registrations and label approvals of endosulfan products to address risks associated with protection of the environment, worker safety and residues in commodities. Some of the principal changes included:

- declaring endosulfan products to be restricted chemical products;
- requiring users of endosulfan to undertake specified training;
- restricting the number of applications for endosulfan per season.

Following this action, the APVMA received new reports of endosulfan residues in beef as a result of spray drift. The APVMA took action to impose mandatory buffer zones, neighbourhood notification requirements before application to cotton, and ultimately cancelled the registration of ultra-low volume endosulfan products.

In 2002 the APVMA, following assessment of additional residue data, further restricted the use of endosulfan on the basis of trade and human health (dietary intake) concerns. These additional restrictions were given effect by suspending product registrations and label approvals, and issuing new instructions for the supply and use of the suspended products. These new instructions included prohibited crop uses (pears, Brussels sprouts and leafy vegetables), some new withholding periods and livestock feeding restraints. The suspensions were in place until 21 December 2005, unless revoked.

Public Consultation

The draft review report was released for a 2 month public consultation period in May 2004. This attracted a total of 85 submissions from the general public, community groups, individual growers, grower organisations, registrants of endosulfan products, and Commonwealth and State agencies. A detailed discussion of the main issues raised during public consultation on the draft review report, including the APVMA responses, is presented in Appendix 2.

Submissions received from the public consultation have resulted in some changes to the findings that were presented in the draft review report.

Occupational Health and Safety Assessment

As an outcome of the interim report of the endosulfan review, additional worker exposure data was required. New data generated under Australian conditions for workers conducting a range of tasks was provided. These involved operations for treating nursery, orchard and broadacre crops by ground and aerial applications and re-entry of workers to broadacre crops. During the public consultation on the draft review report, further crop specific data was provided to allow refinement of worker exposure and re-entry evaluations.

Evaluation of all the available information found that acceptable occupational exposure safety margins could be achieved for all registered nursery, orchard and broadacre uses, with re-entry allowed once the spray deposit has dried. New requirements for personal protective equipment (PPE) and re-entry periods for various tasks have been determined.

Residues Assessment

In response to the requirements of the interim report, additional residues studies were submitted to assess dietary exposure and trade risks from endosulfan use. The initial findings from these studies led to interim action in 2002 to suspend existing endosulfan products, with new instructions for supply and use of the suspended products.

A full assessment of the residues data has resulted in the recommendation to delete certain uses of endosulfan on the basis either of no data being submitted, dietary exposure risk, or trade risk. This includes the late spray for many broadacre crops, and some uses for horticulture crops.

The draft report noted that a key issue was the potential for by-products of cotton and legume vegetables that have been treated with endosulfan to be fed to livestock and cause residue violations in the meat.

As part of the public comment period, the APVMA sought assurances that, should uses on cotton and legume vegetables be retained, appropriate and effective safeguards can and will be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

During the public consultation period the APVMA received numerous submissions from key stakeholders on this issue. A commitment was received from the Australian cotton industry and the livestock industry regarding continued use of endosulfan in cotton. Specifically Cotton Australia and the Cotton Ginners Association have agreed upon a memorandum of understanding (MOU) with the Cattle Council of Australia and the Australian Feedlotters Association that specifies the management practises to be adopted by cotton growers and livestock producers to allow the continued use of endosulfan in cotton.

As no similar assurances could be provided for legume vegetables, these uses have been deleted.

Other issues raised in the public submissions included requests for changes to withholding periods, and inclusion of export slaughter intervals.

Water quality monitoring

The 1998 interim report noted relatively high levels of endosulfan contamination in surface waters in cotton growing areas, with targets set to reduce levels of contamination. Results of river monitoring by the NSW Department of Land and Water Conservation, have shown a significant reduction for both endosulfan detections and concentrations since 1999. these results demonstrate that measures put in place by the APVMA and the cotton industry have been effective in reducing endosulfan contamination in surface waters. Therefore the continued use of endosulfan would not be likely to have an unintended effect that is harmful to the environment.

Endocrine disruption

The 1999 interim report found no evidence of endocrine disruption caused by endosulfan. A US EPA RED (Reregistration Eligibility Decision) report in 2002 identified endosulfan as "a potential endocrine disruptor". The APVMA reassessed their original conclusions in light of this information. This reassessment again concluded that the endocrine disrupting potential of endosulfan is not a significant risk to public health under the existing management controls and health standards.

Summary of review outcomes

The recommendations of the review are that:

- the suspension of registration and label approvals for endosulfan can be revoked;
- product labels will be varied by deleting certain uses, adding new label instructions, amending withholding periods, safety directions and re-entry statements for retained product uses;
- all product registrations for endosulfan can be affirmed; and
- label approvals considered not to contain adequate instructions will be cancelled.

1. INTRODUCTION

The APVMA has completed its review of the active constituent endosulfan, products containing endosulfan and the associated labels. The purpose of this document is to provide a summary of the most recent data evaluated, subsequent to the interim report released in 1998, and of the regulatory decisions reached as a result of the review of endosulfan.

1.1 REGULATORY STATUS OF ENDOSULFAN IN AUSTRALIA

Endosulfan is a broad-spectrum insecticide/acaricide that has been registered in Australia for over 35 years. It is used widely for the control of a large variety of insects and mites in horticultural and agricultural crops, including cotton, cereal, oilseeds, fruit, vegetables and other crops. Endosulfan products are not registered for home garden use.

Endosulfan is an organochlorine chemical, but unlike most other members of this class, it has relatively low persistence in the soil and in animal and human tissue. It also has the benefit of relatively low toxicity to many species of beneficial insects, which prevent population explosions of damaging pests, which in turn would require higher levels of harsher pesticides to control.

Prior to the APVMA review of endosulfan, approximately 900 tonnes of technical grade endosulfan was imported annually into Australia. The greatest use was in cotton (approximately 70%), followed by vegetables (approximately 20%). Since commencement of the review in 1995, endosulfan usage has decreased significantly as a result of interim measures put in place by the APVMA and industry. The introduction of transgenic Bt cotton (genetically altered) is also likely to have a continuing impact on the amount of endosulfan used by the cotton industry.

Current Active Constituent and Product information

There are four active constituent approvals for endosulfan whose approvals were affirmed at the interim report stage. One active constituent has been approved since this time and was subject to outcome of the review.

Approval Number	Active Name	Approval holder
44093*	Endosulfan	MAKHTESHIM-AGAN (AUSTRALIA) PTY LIMITED
44288*	Endosulfan	FARMOZ PTY LTD
44305*	Endosulfan	BAYER CROPSCIENCE PTY LTD
57040#	Endosulfan	BECOT PTY LTD T/AS IMTRADE COMMODITIES

* included in the review # approved subsequently, but subject to outcome of the review.

There are five endosulfan product registrations, all of which are emulsifiable concentrate formulations. All of these registrations are currently under suspension, and instructions for use have been issued for use under specified conditions.

Three of the products (32799, 45570, 45838) are included in the review. Two products (50004, 52163) were registered subsequent to announcement of the review, but are subject to the outcomes as a condition of registration:

Product Number	Name of Product	Label Number(s)
32799 *	Nufarm Endosulfan 350 EC Insecticide	32799/0899 32799/0400 32799/1000 32799/0301 32799/0801
45570 *	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	45570/0299 45570/1099
45838 *	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899 45838/0300 45838/0800
50004 #	Thiodan EC Insecticide [Bayer Cropscience Pty Ltd]	50004/0899 50004/1099 50004/0702
52163 #	Farmoz Endosulfan 350 EC Insecticide	52163/0899

* included in the review # registered subsequently, but subject to outcome of the review.

1.2 REASONS FOR ENDOSULFAN REVIEW

The review of endosulfan was initiated in 1995 because of concerns from its use regarding possible health and environmental effects, residues in commodities and possible trade implications. All aspects of the registration and approvals of endosulfan were considered in the review.

Since the commencement of the review, numerous changes have been made to the registered uses for endosulfan. These have resulted from the implementation of the interim report findings and the availability of new information that questioned the appropriateness of current label instructions.

The interim report required additional OH&S and residues data to be provided, and set targets for reduction in endosulfan levels in surface waters. The potential for endosulfan as an endocrine disruptor has also been reassessed. This Final Review Report considers the assessment of this additional information.

1.3 SCOPE OF THE REVIEW

The initial scope of this review in 1995 covered all active approvals, product registrations and associated label approvals for endosulfan. The review was conducted to determine whether the APVMA could be satisfied that the continued use of products containing endosulfan in accordance with the instructions for their use would not be likely to have any unintended effects that would impact on worker safety, public health, trade and the environment, and whether labels contain adequate instructions.

1.4 REGULATORY OPTIONS

The basis for a reconsideration of the registration and approvals for a chemical is whether the APVMA is satisfied that the requirements prescribed by the Agvet Codes for continued registration and approval are being met. In the case of endosulfan, these requirements are that the use of the active constituents and products in accordance with the instructions for its use:

- would not be an undue hazard to the safety of people exposed to it during its handling or people using anything containing its residues; and
- would not be likely to have an effect that is harmful to human beings; and

- would not be likely to have an unintended effect that is harmful to animals, plants or things or to the environment; and
- would not unduly prejudice trade or commerce between Australia and places outside Australia.

The requirements for product labels are that the label contains adequate instructions. Such instructions include:

- the circumstances in which the product should be used;
- how the product should be used;
- the times when the product should be used;
- the frequency of the use of the product;
- the withholding period after the use of the product;
- the disposal of the product and its container;
- the safe handling of the product.

There are three possible outcomes to the reconsideration of endosulfan active constituents, products and associated labels. Based on the information reviewed the APVMA may be:

- satisfied that the actives, products and their labels continue to meet the prescribed requirements for registration and approval and therefore confirms the registrations and approvals.
- satisfied that the conditions to which the registration or approval is currently subject can be varied in such a way that the requirements for continued registration and approval will be complied with and therefore varies the conditions of registration or approval.
- not satisfied that the requirements for continued registration and approval continue to be met and suspends or cancels the registrations and/or approvals.

2 BACKGROUND

2.1 PREVIOUS REGULATORY ACTION

Interim Report (1998)

In November 1995, the APVMA announced its decision to reconsider approvals and registrations associated with endosulfan, in the first cycle of the Existing Chemicals Review Program (ECRP).

In June 1998, following a comprehensive review of endosulfan, the APVMA released its interim report "*The NRA Review of Endosulfan (August 1998)*". Measures to address the safety of agricultural workers, the environment, and the need to verify residue limits were important outcomes of the review, and relevant label changes were required to take effect by 30 June 1999. This action substantially restricted the use of endosulfan.

Some minor changes to public health standards were recommended, resulting in a reduction of the acceptable daily intake (ADI).

These controls were considered necessary for the continued use of endosulfan. Existing uses were allowed to remain on an interim basis while new data was generated to support uses in the longer term.

A summary of the changes and restrictions arising from the Interim Review are shown in Table 2.1.

TABLE 2.1:
Summary of APVMA regulatory actions for endosulfan determined in June 1998

Key Issues	Regulatory Actions
Control of access	• Endosulfan declared a restricted chemical. • Endosulfan products must not be supplied to a person who is not authorised. Authorised persons require training certification.
Environmental contamination of streams and rivers	• 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.
Insufficient worker exposure data	• Requirement for the generation of worker exposure data for certain agricultural uses of endosulfan, under Australian conditions, by 31 December 1999. • New label statement promoting use of enclosed cabs for ground spray applications. • New label statement specifying a 2-day re-entry period. • New label safety directions.
Insufficient residues data in commodities	• Requirement to generate residue data by 30 June 2000 to support existing uses.
Potential for meat residues	• Restrictions placed on orchard grazing and feeding treated crop products to cows producing milk for human consumption. • Labels changed to include recommended withholding periods for use of crop by-products or fodder as animal feed.

Endosulfan residue crisis in exported beef of late 1998 and early 1999

In November and December 1998, detection of endosulfan residues in beef emerged in cotton growing areas. These problems were severe enough to affect Australia's reputation with its international trading partners and to threaten the viability of segments of the domestic beef industry.

As a result, in March 1999 the APVMA mandated additional changes to all labels to avoid undue prejudice to Australia's international beef trade. These changes, effective from 1 July 1999, were to apply only to use on cotton and were in addition to the changes already required as a result of the outcomes of the interim report. The most significant new restrictions imposed were as follows:

- An absolute limit of 3 sprays (or equivalent) of endosulfan per cotton crop per season;
- Endosulfan to be applied by air only during specified time windows (15 Nov. to 15 Jan. for EC, 1 Dec. to 15 Jan. for ULV);

- Aerial application restricted to crops over a specified height;
- Mandatory downwind buffer zones required unless neighbour gives written permission to waive buffer;
- Mandatory prior notification of neighbours in all directions surrounding the sprayed area;
- Use of high-volume, large-droplet-placement technology required for all EC applications whether by air or by ground.

Spray drift from ULV products

In March 2001, the APVMA cancelled all registrations and label approvals for ULV products because of further concern over contamination of livestock from spray drift and the resulting risk to Australia's export trade.

Suspension of registration and label approvals

As discussed above, additional residues data were required as an outcome of the interim report. Following assessment of this additional data, two areas of immediate concern were identified and addressed. These related to human dietary risk from consumption of pears, Brussels sprouts or leafy vegetables, and prejudice to Australia's international meat trade arising from endosulfan residues in beef.

As part of the actions to address these concerns, the APVMA suspended product registrations and label approvals of all (5) endosulfan products in September 2002, and undertook recall action. New instructions for use were issued to allow continued supply of suspended product that specified prohibited crop uses, new withholding period statement for pears and numerous feeding restraints.

2.2 OVERSEAS REGULATORY STATUS

North America

In the United States endosulfan is registered for similar use patterns as in Australia.

In 2002, the US EPA released a RED (Re-registration Eligibility Decision). Following an assessment of data, it was determined that endosulfan products pose occupational and ecological risks. However, the US EPA believes that these risks can be mitigated through measures that include deletion of some uses, reduction in maximum application rates, inclusion of buffer zones, all products to be restricted, use of closed mixing/loading systems, use of closed cabs for certain situations, and increases to re-entry intervals. The US EPA is also requiring additional data to confirm this decision. In June 2005 the US EPA recived requests from registrants of endosulfan products to voluntary cancel uses on succulent beans, spinach, grapes and peacans.

Canada is also conducting a re-evaluation of endosulfan, which should be completed in 2006. Canada is closely monitoring the outcomes of US regulatory actions.

Europe

Endosulfan products are registered for use in a number of EU countries (including UK), but are either restricted or banned in some others. A re-evaluation of endosulfan products is currently in preparation by the EU. In June 2005 the EU Commission released notification concerning the non-inclusion of endosulfan in Annex 1 to the Council Directive 91/414/EEC and the withdrawal of authorisations for plant protection products containing the active substance endosulfan.

JMPR

Endosulfan was previously evaluated by JMPR for residues and toxicology in 1993. A re-evaluation is proposed based on residues, for September 2005.

2.3 ALTERNATIVE PRODUCTS

Alternative products to endosulfan are available for all use patterns. However, endosulfan has a number of important advantages in that it is:

- inexpensive;
- soft on beneficial insects, thus minimising post-application population explosion of harmful insects; and
- a different chemistry, useful for resistance management.

It is anticipated that increasing use of genetically modified cotton will reduce reliance on pesticides such as endosulfan in future.

2.4 Public Consultation

The draft review report was released for a 2 month period public consultation period in May 2004. This attracted a total of 85 submissions from the general public, community groups, individual growers, grower organisations, registrants, Commonwealth and State agencies. A detailed discussion of the main issues raised during public consultation on the draft review report, including the APVMA responses, is presented in Appendix 2.

A key issue from the Draft Review Report was the continued use of endosulfan on cotton and legume vegetables. The APVMA sought assurances that, were uses for cotton and legume vegetables to be retained, appropriate and effective safeguards could and would be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

Other public submissions to the review included requests for changes to withholding periods where this was supported by submitted data, questioned the appropriateness of the dermal absorption factor used in the assessment and provided general comments in regard to the adequacy of labelling.

The public submissions have resulted in some changes to the Occupational Health and Safety and the residues and trade findings that were presented in the draft review report (for details, refer to the OH&S and Residues sections below).

3. RESIDUES & TRADE ASSESSMENT

3.1 INTRODUCTION

The 1998 endosulfan interim report identified the need for additional residue data to support existing uses and MRLs. If the use of endosulfan was to continue the following additional data requirements were determined: Where the requested data were not submitted and MRLs could not be supported or established, the uses would be deleted.

- *Animal feeds* – data for forages, fodder or hays of such plants as cereals (including sorghum and maize), pastures, canola, sunflowers, legume vegetables, potato, peanuts, and legume crops.
- *Human foods* – data for all commodities that were assigned a temporary MRL in the MRL Standard.
- *Processing studies* – cereals, fruits (citrus, apples and grapes), cotton and other oilseeds.
- *Animal commodities* – animal transfer studies in cattle and poultry, including analyses of milk and eggs, respectively.

As an outcome of the interim report, temporary MRLs were recommended for a number of crops to allow additional data to be generated.

Interim regulatory action in conjunction with the temporary MRLs, included limiting the number of applications of endosulfan per season to all crops and introducing residue management strategies with regular surveillance and monitoring in targeted areas. Crop withholding period statements were developed together with animal management statements, to allow treated animal feed commodities to be used whilst managing residues in livestock.

Supplementary residues data received by the APVMA were evaluated and an interim residues report was completed in September 2002. Recommendations in the interim report led to the suspension of existing endosulfan products and new instructions were issued for the supply and use of suspended products, as discussed in section 5.2.1. A copy of the suspension notice is attached to the Residues Technical Report (Appendix 1).

In this report, the data and other information received by the APVMA subsequent to the interim report are reviewed and form the basis of residues conclusions for final regulatory action.

3.1.1 MRLs and Label Withholding Period Statements (superseded June 2005)

The MRLs for endosulfan (superseded June 2005) are listed below:

Table 1		
Code	**Food Commodity**	**MRL (mg/kg)**
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2
FB 0018	Berries and other small fruits	T2
VB 0400	Broccoli	T2
VB 0041	Cabbages, head	T2
VB 0404	Cauliflower	T2
GC 0080	Cereal grains	T0.2
FC 001	Citrus fruits	T2
OC 0691	Cotton seed oil, crude	T0.5
MO 0105	Edible offal (mammalian)	T0.2
PE 0112	Eggs	T*0.05
VC 0045	Fruiting vegetables, cucurbits	T2
VO 0050	Fruiting vegetables, other than cucurbits	T2
VP0060	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 0009	Pome fruits	T2
PO 0111	Poultry, edible offal of	0.2
PM 0110	Poultry meat [in the fat]	0.2
VD 0090	Pulses	T1
GC 0649	Rice	T0.1
VR 0075	Root and tuber vegetables	T2

VA 0388	Shallots	T2
VS 0078	Stalk and stem vegetables	T2
FS 0012	Stone fruits	T2
DT 1114	Tea, Green, Black	T30
TN 0085	Tree nuts	T2

Table 4[1]

Code	**Animal Feed Commodity**	**MRL (mg/kg)**
	Primary feed commodities	0.3

As part of the interim regulatory action in 1998, the MRL for leafy vegetables (including Brassica leafy vegetables) was deleted and the MRL for Brassica (cole and cabbage) vegetables, head cabbages, flowerhead Brassica was deleted and replaced with individual entries for broccoli, cabbage and cauliflower. These changes were associated with concerns regarding short-term dietary exposures.

The following withholding period statements and feeding restraints were present on product labels until June 2005, specifically for residue management in crops and in particular livestock that were fed treated crops and crop fractions.

Withholding period statements and feeding restraints

Crop	**Withholding period/feeding restraint**
Beetroot, cucurbits, green beans, green peas, tomatoes	DO NOT HARVEST FOR 2 DAYS AFTER APPLICATION
Cape gooseberry, capsicums, carrots, eggplant, okra, onions, peanuts, potatoes, shallots, sweet corn, sweet potatoes, taro	DO NOT HARVEST FOR 7 DAYS AFTER APPLICATION
Avocados, bananas, berry fruit, blueberries, cashews, citrus, currants and related fruit, custard apples, grapes, guavas, kiwifruit, longans, lychees, macadamias, mammey apples, mangoes, passion fruit, pawpaws, pecans, persimmons, pistachios, pome fruit, pomegranates, rambutans, raspberries, sapodillas, strawberries, tamarillos	DO NOT HARVEST FOR 14 DAYS AFTER APPLICATION
Adzuki beans, canola (oilseed rape), cereals, chickpeas, cotton, cowpeas, faba beans, field peas, fodder crops (clover, chou moellier, lucerne, medics, peas), linseed, lupins, maize, mung beans, oilseeds, pastures, pigeon peas, safflower, sorghum, soybeans, sunflowers, vetch	DO NOT HARVEST FOR 4 WEEKS AFTER APPLICATION
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	

[1] Recommended maximum residue limits for pesticides in animal feed commodities.

Pasture Forage and Pasture Seed Crops	DO NOT GRAZE OR CUT FOR STOCKFOOD FOR 4 WEEKS AFTER APPLICATION. FOR FOLIAR APPLICATIONS, A 42 DAYS SLAUGHTER INTERVAL APPLIES
DO NOT FEED TREATED CROPS OR CROP PARTS (EXCEPT COTTONSEED/MEAL) TO LACTATING COWS PRODUCING MILK FOR HUMAN CONSUMPTION.	

Where there has been at least 4 weeks since the last endosulfan application, the following slaughter intervals are still required to avoid Maximum Residue Limit violations

Crop/Commodity	***Observed Crop Harvest WHP***	***Required Animal Management***
Cottonseed/meal	*4 weeks*	*Nil slaughter interval*
Apples & apple pomace	*4 weeks*	*42 day slaughter interval*
Grain legumes & pulse fodder/stubble	*4 weeks*	*42 day slaughter interval (foliar application only)*
Cereal grains	*4 weeks*	*Nil slaughter interval*
Cereal fodder/stubble	*4 weeks*	*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 (e.g. leafy vegetables)	*4 weeks*	*42 day slaughter interval*
Citrus & citrus pulp	*4 weeks*	*42 day slaughter interval*

Note below that maize and sorghum fodder require at least an 8 week WHP combined with a 42 day slaughter interval to avoid Maximum Residue Limit violations. For certain commodities where the WHPs shown below have been observed, the following animal management measures are still required to avoid Maximum Residue Limit violations.

Crop/Commodity	***Observed Crop Harvest WHP***	***Required Animal Management***
Cotton trash	*Not applicable*	*Do not feed to animals*
Green beans, green peas	*2 days*	*Do not feed to animals*
Maize grain	*8 weeks*	*Nil slaughter interval*
Maize fodder	*8 weeks*	*42 day slaughter interval*
Other vegetables (beetroot, cucurbits and tomato)	*2 days*	*Do not feed to animals*
Peanut hay	*7 days*	*42 day slaughter interval*
Sorghum grain	*8 weeks*	*Nil slaughter interval*
Sorghum fodder	*8 weeks*	*42 day slaughter interval*

The following additional withholding periods and feeding restraints were introduced as part of the suspension of endosulfan products in September 2002:

Withholding periods and feeding restraints introduced in September 2002 and superseded in June 2005

- Pears: Do Not Harvest for 28 Days After Application
- Do Not Feed Apple Pomace, Citrus Pulp/Peel, Grape Marc/Pomace To Livestock
- Do Not Feed Pea Vines or Bean Trash to Livestock
- Do Not Feed Fodder, Stubble Or Hay of Pulse Crops (Adzuki Beans, Chickpeas, Cow Peas, Faba Beans, Field Peas, Lupins, Mung Beans, Navy Beans and Pigeon Peas) To Livestock
- Do Not Feed Treated Cow Peas, Field Peas and Pigeon Peas to Livestock

- Do Not Feed Cereal Grains to Livestock
- Do Not Feed Straw, Fodder or Trash from Treated Cereal Crops To Livestock
- Do Not Feed Sunflower Seed, Safflower Seed or Linseed to Livestock
- Do Not Feed Fodder, Stubble or Trash from Oilseed Crops (Canola, Cotton, Linseed, Peanuts, Safflower, Soya Beans, Sunflowers) To Livestock
- Do Not Feed Cotton Fodder, Stubble or Trash To Livestock
- Do Not Cut for Stockfeed or Allow Livestock to Graze: vetch, lucerne (seed crops), medics (seed crops), clover (seed crops), chou moellier, forage cereals and pastures (all with heliothis use rates)
- Do Not Feed Wrapper Leaves of Brassica and Cole Crops (Cabbage, Cauliflower and Broccoli) or Sweet Corn Trash to Livestock
- Do Not Feed To Livestock Any Treated Commodity Mentioned Above Which Has Been Bailed or Used in Silage

3.1.2 Label Use Patterns

Crop use patterns as shown on revised interim labels are given in Residues technical report (Volume 2 of this document).

3.2 DISCUSSION

In response to the interim regulatory requirements for endosulfan, metabolism studies, animal transfer studies, supervised crop trials, storage stability and processing studies have been submitted. The findings from those studies and associated recommendations are discussed in the following sections.

3.2.1 Citrus fruit

Data for oranges, mandarins and lemons were provided from trials conducted in Australia, Italy, Greece and Spain. Data for processed commodities such as juice and pomace were also submitted.

Registered use patterns in citrus allow spraying at concentrations ranging from 20 g ai/100L (spined citrus bug, bronze orange bug) to 70 g ai/100L or 735 g ai/ha (heliothis, citrus plant hopper, leaf hopper), with a 14 day withholding period. However, the citrus industry provided data for a lower spray concentration to better reflect current practices in the industry. Therefore the new 1× and 2× spray concentrations are 10.5 and 21 g ai/100L, with a proposed withholding period of 3 days.

Overseas data were generated using spray concentrations of 37.5 and 112.3 g ai/100L, which are in excess of the new citrus use pattern. These data are not suitable for establishment of an MRL, however the processing information can be used to determine processing factors (PF) for juice and pomace.

Data for oranges, mandarins and lemons were generated in Australia. The data corresponding to the proposed GAP are summarised below:

Commodity, Trial	Spray Conc.	WHP	Total residues (mg/kg)
Oranges, Vic	10.5 g ai/100L 21 g ai/100L	3 3	0.049 0.22
Oranges, SA	10.5 g ai/100L 21 g ai/100L	3 3	0.078 0.034 (pulp); 0.38 (peel)
Lemons, Vic	10.5 g ai/100L 21 g ai/100L	3 3	0.17 0.70
Lemons, Qld	10.5 g ai/100L	3	0.033

	21 g ai/100L	3	<0.02 (pulp); 0.36 (peel)
Lemons, SA	10.5 g ai/100L 21 g ai/100L	3 3	0.16∗ 0.34
Mandarins, Qld	10.5 g ai/100L 21 g ai/100L	3 3	0.11 0.18
Mandarins, SA	10.5 g ai/100L 21 g ai/100L	3 3	0.071 0.14

∗ Level of 0.036 mg/kg present in untreated control sample.

Residues in citrus fruit range from 0.033 to 0.17 mg/kg at 3 days following application at the 1× spray concentration. Residues in citrus fruit are in rank order: 0.033, 0.049, 0.071, 0.078, 0.11, 0.16 and 0.17 mg/kg. An MRL of 0.3 mg/kg is recommended for citrus fruit with highest residues (HR) of 0.078, 0.11 and 0.17 mg/kg for oranges, mandarins and lemons, respectively and a supervised trial medium residues (STMR) of 0.078 mg/kg.

In the overseas trials, spray concentrations of 37.5 and 112.3 g ai/100L (3.6× or 10.7×) were employed. Endosulfan residues in pulp, peel, juice and pomace were reported. In nine overseas trials, there was a 6-fold difference between residues found in peel vs whole fruit. In two Australian trials however, the difference between peel and whole fruit was 2-fold.

Residues in juice were <0.02 mg/kg in three orange trials; the mean PF was 0.12. The mean PF for wet pomace was 2.3. To estimate the livestock exposure from feeding of dry pomace, an STMR-P of 0.45 mg/kg is calculated (0.08 mg/kg × 2.3 = 0.18 mg/kg wet wgt; 0.45 mg/kg dry weight). This figure is included in the livestock dietary burden table (section 2.18).

Using an HR of 0.17 mg/kg in whole fruit and the PF for pomace, residues in wet pomace would be 0.17 × 2.3 = 0.39 mg/kg or 0.97 mg/kg on a dry weight basis. An MRL of 2 mg/kg is recommended for citrus pulp and pomace, dry.

3.2.2 Pome fruit

The current use pattern for pome fruit is application at 66.5 g ai/100L with a withholding period of 14 days. Residues data were provided from trials conducted in Australia, Italy, France and Spain. Processing data for juice, cider and pomace were also submitted.

Overseas data for apples were generated using spray concentrations of 56.5 and 113 g ai/100L (0.8× and 1.7×). In the Australian trials, 1× and 2× spray concentrations were used on apples and pears. The data that are comparable to GAP are tabulated below:

Commodity, Trial	Spray Conc.	WHP	Total residues (mg/kg)
Apples, NSW	66.5 g ai/100L	14	0.29
		21	0.27
		14	0.38
Apples, Qld	66.5	14	0.53
Apples, Spain	56.5 g ai/100L	12	0.03
		21	<0.01
		28	<0.01
Apples, Spain	56.5 g ai/100L	12	0.05
		21	0.06
		28	<0.01
Apples, France	57 g ai/100L	13	<0.01
		21	<0.01
		28	<0.01
Apples, Italy	56.5 g ai/100L	14	0.23
		21	0.14
		28	0.11

Apples, Italy	56.5 g ai/100L	14	0.04
		21	0.08
		28	0.03
Pears, Vic	66.5 g ai/100L	14	0.79
		21	0.42
Pears, SA	66.5 g ai/100L	14	0.44
		21	0.37

Allowing for a ±30% difference in spray concentration at 14 days, the following residues correspond to GAP in rank order: <0.01, 0.03, 0.04, 0.05, 0.23, 0.29, 0.38, 0.44, 0.53 and 0.79 mg/kg. Based on the data at 14 days, the current temporary MRL of 2 mg/kg is appropriate with an HR of 0.53 mg/kg for apples[2] and 0.79 mg/kg for pears.

Applying the HR value for pears in the short-term dietary estimates, the intake exceeds the acute reference dose (ARfD) for the 2 – 6 year group and approaches the ARfD for the general population (99%). To refine the short-term estimate, the horticulture industry agreed to extend the withholding period for apples and pears from 14 days to 28 days.

The HR for apples at 28 days after treatment is 0.11 mg/kg, from trial data generated in Italy. For pears, the highest residues expected at 28 days would be 0.21 mg/kg, using extrapolation from Australian trial data.

It is recommended that the current temporary MRL of 2 mg/kg be amended to 1 mg/kg with a withholding period of 28 days. An STMR is not estimated for the group.

Residues in apple juice in a single Australian trial were 0.022 mg/kg and residues in cider from Italian trials were <0.01 mg/kg. The PFs for juice and cider were 0.06 and 0.04, respectively.

The mean processing factor for wet pomace, calculated from three trials including one Australian trial, is 2.1. Using a HR of 0.11 mg/kg for apples (28 days), residues in wet pomace will approximate 0.23 mg/kg. A processing factor of 5.8 is calculated in the Australian trial for dry pomace. Therefore applying the dry pomace factor to the HR gives a value of 0.64 mg/kg for dry pomace. An MRL of 1 mg/kg is recommended for apple pomace, dry.

3.2.3 Grapes

Currently, there is a temporary MRL of 2 mg/kg for berries and other small fruits, which corresponds to registered uses of endosulfan on grapes, currants, blueberries and strawberries. Overseas data were provided for grapes and processed commodities. The registered use pattern for grapes allows application at a spray concentration of 66.5 g ai/100L with a withholding period of 14 days. In trials conducted in Italy and Spain, concentrations of 113 g ai/100L were employed. As the spray concentrations in the studies do not correspond to GAP in Australia, the data do not support existing use patterns. Therefore, the use pattern for grapes should be deleted from all product labels. Similarly, as data were not provided for other berry fruit such as blueberries, currants and strawberries, these uses must also be deleted from product labels. It is recommended that the temporary MRL for berries and other small fruits be withdrawn from the MRL Standard.

[2] Data from the National Residues Survey monitoring program indicated that total endosulfan residues found in apples ranged from 0.05 mg/kg to 0.26 mg/kg. These data were obtained from 1238 samples over the period of 1998 – 2003; various varieties were sampled. The limit of reporting was 0.05 mg/kg.

3.2.4 Tropical and sub-tropical fruits – inedible peel

The Codex crop group for tropical fruits – inedible peel includes avocados, bananas, custard apples, kiwifruit, longans, lychees, mammey, mangoes, passionfruit, pawpaw, persimmon, pomegranate, rambutan, sapodilla and tamarillo, all of which are included on registered product labels. Supplementary residues data were generated recognising that there was no support for use on bananas, and that extrapolation to minor crops would be made from the data set provided. In addition, withholding periods shorter than 14 days (as indicated on current labels) were requested to better reflect industry practices. Australian residues data were provided for avocado, custard apples, mangoes, pawpaw, persimmon and lychees. GAP in Australia is application at spray concentrations of 52.5 – 70 g ai/100L with withholding periods of 7 or 14 days, depending on the fruit.

Residues data which correspond to GAP for the various fruits, are summarised below:

Commodity, Trial	Spray Conc.	WHP (days)	Total residues (mg/kg)
Avocado, Qld	70 g ai/100L	14	0.02
Avocado, Qld	70 g ai/100L	14	0.065
Custard apple, Qld	70 g ai/100L	7	0.1
Custard apple, Qld	70 g ai/100L	7	0.34
Mango, NSW	70 g ai/100L	7	0.20
Mango, Qld	70 g ai/100L	7	0.17
Pawpaw, Qld	70 g ai/100L	7	0.18
Pawpaw, Qld	70 g ai/100L	7	0.095
Persimmon, Qld	70 g ai/100L	7	0.53
Persimmon, Qld	70 g ai/100L	7	0.89
Lychee, Qld	52.5 g ai/100L	7	0.95, 1.62①
Lychee, Qld	52.5 g ai/100L	7	0.84, 1.16①

① Two replicate samples combined and analysed.

The portion of the commodity to which the MRL applies is the whole commodity after removal of the stone or seed, but calculated on a whole fruit basis.

Looking at the data across the whole group, residues are in rank order: 0.02, 0.065, 0.095, 0.1, 0.17, 0.18, 0.20, 0.34, 0.53, 0.84, 0.89, 0.95, 1.16 and 1.62 mg/kg. On the basis of the data set provided, the temporary MRL of 2 mg/kg is appropriate for the whole crop group, with respect to existing and proposed use patterns. The highest residues for avocado, custard apple, mango, pawpaw, persimmon and lychee are 0.065, 0.34, 0.20, 0.18, 0.89 and 1.62 mg/kg, respectively. For the group, an STMR of 0.27 mg/kg is estimated. It should be noted that tamarillo is also to be included in this group.

3.2.5 Bulb vegetables

The current MRLs for endosulfan on bulb vegetables are T0.2 mg/kg for onions and T2 mg/kg for shallots. These correspond to application at a maximum rate of 735 g ai/ha and withholding periods of 7 days. As residues data for these crops (or any bulb vegetable) have not been provided, the existing use patterns and temporary MRLs will be deleted as they are no longer supported.

3.2.6 Brassica vegetables

Australian data were provided for broccoli, cauliflower, cabbage, and Brussels sprouts. Registered use patterns allow application at 735 g ai/ha or 66.5 g ai/100L with a withholding period of 2 days (cole crops). The horticulture industry has requested a withholding period of 7 days for Brassica vegetables. Data that correspond to GAP in Australia are summarised below:

Commodity, Trial	Spray Conc.	WHP (days)	Total residues (mg/kg)
Broccoli, Qld	66.5 g ai/100L	7	0.29

Broccoli, VIC	66.5 g ai/100L	7	0.17
Cauliflower, WA	66.5 g ai/100L	7	0.10
Cauliflower, VIC	66.5 g ai/100L	7	0.016
		7	0.094
Cabbage, Qld	66.5 g ai/100L	7	0.098
Cabbage, VIC	66.5 g ai/100L	7	0.031
		7	0.026
Brussels sprouts, SA	66.5 g ai/100L	7	1.9
Brussels sprouts	6.5 g ai/100L	7	0.14

Residues in Brassica at day 7 are in rank order: 0.016, 0.026, 0.031, 0.094, 0.098, 0.10, 0.14, 0.17, 0.29 and 1.9 mg/kg. Highest residues in broccoli, cauliflower and cabbage are 0.29, 0.1 and 0.098 mg/kg, respectively. The highest residue of 1.9 mg/kg in Brussels sprouts was found following application at 1.8× the maximum rate; scaling for rate, residues of 1.05 mg/kg are estimated at 7 days. Taking into consideration the high value, and only one other data point at GAP for Brussels sprouts, it is recommended that the Brussels sprouts use pattern be removed from product labels. On the basis of the data provided for broccoli, cabbage and cauliflower, MRLs of 1 mg/kg are recommended for broccoli, head cabbage and cauliflower. An STMR of 0.096 mg/kg is estimated for the chronic dietary exposure for broccoli, cauliflower and cabbage.

3.2.7 Cucurbits

Endosulfan is registered for use on cucurbits, with application at 66.5 g ai/100L and a withholding period of 2 days. Residues data were provided from trials conducted in Australia, Italy and Spain. In the overseas trials in melons, residues were determined in the pulp, peel and whole fruit. The horticulture industry requested that the current withholding period be extended from 2 days to 7 days. Data corresponding to Australian GAP are summarized below:

Commodity, Trial Site	Spray Conc. (g ai/100L)	WHP (days)	Total residues (mg/kg)
Musk melon, Italy	56.5	3	<0.15 (whole fruit)
			<0.15 (pulp)
			0.22 (peel)
Musk melon, Italy	56.5	3	0.19 (whole fruit) 0.22
			<0.15 (pulp)
			0.48 (peel)
Rockmelon, VIC	66.5	3	0.55
Cucumber, NSW	66.5	7	0.12①
Cucumber, Qld	66.5	7	0.094①
Zucchini, NSW	66.5	3	0.09
Zucchini, Qld	66.5	3	0.055
Zucchini, Qld	66.5	3	0.087
Zucchini, WA	66.5	3	0.049

① Higher values selected at longer WHPs.

Using ±30% allowance in the spray concentration, Italian trial data for melons can be compared to the Australian spray concentration of 66.5 g ai/100L. Residues in the edible portion of the musk melon were <0.15 mg/kg in all of the overseas trials, at spray concentrations ranging 1 – 2.8× the Australian spray concentration.

Residues in cucurbits at 3 days after application are in rank order: 0.049, 0.055, 0.087, 0.090, 0.094, 0.12, <0.15, 0.22 and 0.55 mg/kg. An MRL of 1 mg/kg is recommended for cucurbits with a withholding period of 3 days. The HRs in rockmelon, cucumber and zucchini are <0.15 (pulp) or 0.55 (whole fruit), 0.12 and 0.09 mg/kg, respectively and the STMR is 0.094 mg/kg for the group.

Comments were received during the public consultation phase in relation to feeding of waste or cull melons to livestock, particularly cattle. As the proposed MRL for cucurbits exceeds the

current Primary Feed Commodity MRL of 0.3 mg/kg, the following feeding restraint has been included on product labels:

Do Not Feed Treated Melon Crops Or Melons To Livestock

3.2.8 Fruiting vegetables

Australian data were provided for capsicum, tomato, eggplant and sweet corn as being representative members of the crop group, which also includes okra and cape gooseberry. The current use pattern is application at 66.5 g ai/100L or 735 g ai/ha and withholding periods of 2 days for tomatoes and 7 days for cape gooseberries, capsicums, eggplant, okra and sweet corn. The horticulture industry has requested a withholding period of 3 days for capsicums and tomatoes.

In the residue trials the application rates employed were 1× and 2× the maximum application rate, with sampling intervals up to 14 days. The data that correspond to GAP (proposed) are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Capsicum, Qld	735	3	0.16
Capsicum, SA	735	3	0.40
Tomatoes, Qld	735	3	0.056
Tomatoes, Vic	735	3	0.069
Tomatoes, NSW	735	3	0.094
Eggplant, NSW	735	7	<0.02
Eggplant, Qld	735	7	0.055
Eggplant, Vic	735	7	<0.02
Eggplant, Qld	735	7	<0.02
Sweet corn, Qld	735	7	<0.02
Sweet corn, Vic	735	7	<0.02
Sweet corn, NSW	735	7	<0.02

Residues that correspond to GAP are in rank order: <0.02 (6), 0.055, 0.056, 0.069, 0.094, 0.16 and 0.40 mg/kg. The HRs for capsicum, tomato, eggplant and sweet corn are 0.40, 0.094, 0.055 and 0.02 mg/kg, respectively, with an STMR of 0.038 mg/kg. An MRL of 1 mg/kg is recommended for the fruiting vegetables group.

In relation to sweet corn fodder/trash, the following restraint was included as part of the interim regulatory action for endosulfan:

- *Do Not Feed Sweet Corn Trash To Livestock.*

On registered product labels, there had previously been no directions regarding the feeding of sweet corn fodder or trash to livestock. As data specifically for sweet corn fodder or trash were not provided, some extrapolation can be made from sorghum forage and trash. The use pattern for sorghum is detailed in section 2.14 under cereal crops, where application is at 735 g ai/ha with a withholding period of 4 weeks. Endosulfan residues in sorghum forage/fodder ranged from 3 to 79 mg/kg in samples taken at 26 to 35 days after two applications. As the withholding period for sweet corn is 7 days, it is possible that residues in sweet corn fodder/trash may be even higher than the levels found in sorghum forage/fodder at 26 to 35 days.

As there was no previous feeding restraint regarding sweet corn fodder/trash and it is typical practice for sweet corn fodder to be used as a livestock feed, it is an outcome of the review that the sweet corn use pattern has been deleted from product labels, as the likely exposure to livestock from sweet corn fodder and trash may be at levels that are unacceptable in relation to existing animal commodity MRLs. Deletion of the use pattern does not result in a change to the MRL or STMR for the crop group.

3.2.9 Leafy vegetables

The Codex classification for leafy vegetables includes Brassica leafy vegetables and crops such as chard (silverbeet), Chinese cabbage, choi sum, leafy lettuce varieties (cos lettuce, endive, rocket), cress, Japanese greens (mizuna, indian mustard, komatsuna), head lettuce, spinach, pak choi, bok choi and a variety of other salad greens. Australian residues data were provided for bok choi, silverbeet, and leafy lettuce, which are considered representatives of the crop group.

In addition to the data that were generated in Australia there were several published reports of endosulfan residues in leafy vegetables, which are summarised in Residues Appendix 3. These include JMPR data (1989), review articles and information available from published papers.

The current registered uses of endosulfan on leafy vegetables (cole crops and leaf vegetables), silverbeet and spinach include application at 735 g ai/ha or 66.5 g ai/100L with withholding periods of 2 days for cole crops and silverbeet and 7 days for spinach. There is no specific withholding period statement for other leafy crops, where the use pattern is listed as *cabbages, cauliflower & other cole crops & leaf vegetables* on some product labels. For the purposes of data interpretation, the withholding period closest to label directions is taken as being nil or 0 days.

The data that correspond to GAP are summarised below:

Commodity, Trial Site	Spray conc. (g ai/100L)	WHP (days)	Total residues (mg/kg)
Bok choi, Vic	66.5	0	3.4
Bok choi, Qld	66.5	0	29
Silverbeet, Vic	66.5	0	6.1
Silverbeet, Qld	66.5	0	18
Leafy lettuce, Vic	66.5	0	3.4
Leafy lettuce, Vic	514 g ai/ha	0	16
Leafy lettuce, NSW	66.5	0	16
Leafy lettuce, NSW	66.5	0	6.5
Leafy lettuce, Qld	66.5	0	1.54

There is a large variation in the residues present in the different crops, with levels ranging 1.54 – 29 mg/kg. As there is no clear withholding period statement for leafy vegetables, the 0 day data are taken as being reflective of the levels that would be found at harvest in some members of the crop group. The residues are in rank order: 1.54, 3.4 (2), 6.1, 6.5, 16 (2), 18 and 29 mg/kg.

Using the mean 0 day values from overseas data for the various leafy crops and scaling for the Australian application rate, estimated endosulfan residues in chard, spinach, leaf lettuce, head lettuce, endive and cos lettuce ranged from 7.9 mg/kg to 20 mg/kg. This range of values is comparable to the 0 day data from the Australian trials in silver beet and leafy lettuces. The published data support the findings in the Australian trials.

Based on the data reviewed, an MRL of 40 mg/kg would be recommended for leafy vegetables, with HRs of 18 mg/kg for silverbeet, 29 mg/kg for bok choi and 16 mg/kg for leafy lettuce. As there is a large variation in residues, an STMR cannot be estimated for the crop group.

A longer withholding period has been considered to determine if residues would comply with the current temporary MRL of 2 mg/kg. However, using the 14 day data, the acute reference dose is still exceeded for both the 2 – 6 year age group and the general population. Based on the short-term estimate of intake for both the 2 – 6 year subpopulation and the general population, it is recommended that the leafy vegetables use patterns should be deleted from all product labels, as the estimated dietary exposure is unacceptable using current methods of assessment (section 2.21).

Action was taken to withdraw registered uses of endosulfan on leafy vegetables as part of the suspension of products in September 2002.

3.2.10 Legume vegetables

Residues data were provided for green peas and green beans from trials conducted in Italy, France and Australia. In the overseas trials, samples of green plant material were collected to give an indication of residues that may be present in animal feed commodities, such as pea vines. Processing data were also generated with residues being determined in canned peas.

Current use patterns allow application at 735 g ai/ha with a withholding period of 2 days. The horticulture industry has requested that the withholding period be extended to 7 days for both crops. Data that correspond to proposed GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Green beans, Qld	735	7	0.15
Green beans, Tas	735	7	<0.02
Green beans, Vic	735	7	0.092
Green peas, Qld	735	7	0.082
Green peas, Qld	735	7	0.12
Green peas, Vic	735	7	0.37
Plant material, France	749	7	1.65 (6.6 dry wgt)∗
Plant material, France	780	7	2.2 (8.8 dry wgt)
Plant material, Italy	780	7	1.24 (4.9 dry wgt)
Plant material, Italy	750	7	2.67 (10.7 dry wgt)
Pea hay, Qld	735	7	3.1 (12.4 dry wgt)

∗ Using 25% DM for green material.

Data for green peas and beans that correspond to GAP are in rank order: <0.02, 0.082, 0.092, 0.12, 0.15 and 0.37 mg/kg. The HR for green peas is 0.37 mg/kg and for green beans is 0.092 mg/kg. An MRL of 1 mg/kg is recommended for legume vegetables with a withholding period of 7 days; an STMR of 0.11 mg kg is estimated for the group.

In relation to animal feed commodities, the highest residues found in plant material were 12.4 mg/kg on a dry weight basis, with values ranging from 6.6 to 12.4 mg/kg. The current primary feed commodity MRL in Table 4 of the MRL Standard is 0.3 mg/kg. As an interim measure, the following recommendation was made as part of the suspension of endosulfan products:

- *Do Not Feed Treated Pea Vines or Bean Trash to Livestock*

On registered product labels, there are directions regarding the feeding of green beans and green peas; crop by-products such as pea vines and bean hay are however not specifically mentioned. The directions regarding green beans and green peas are:

- *Do Not Feed To Animals*

Although it is recognised that green peas and beans are primarily grown for human consumption, it is claimed that pea hay and other legume hays and vines are routinely cut and fed to livestock or grazed by livestock following harvest. Due to this potential exposure and the associated trade implications, two alternative approaches were considered for the use of endosulfan on legume vegetables:

1. continue to permit the use, with the following label restraint:

- **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**

2. delete the uses.

As a feeding restraint would be contrary to common livestock grazing and feeding practices, the APVMA has concluded that the use patterns for green beans and peas will be deleted from product labels, as the likely exposure to livestock from feeding of pea and bean vines and hay may be at levels that are unacceptable in relation to existing animal commodity MRLs.

These options are discussed more fully in section 3.2.21.

3.2.11 Pulse crops

Endosulfan is registered for use on a number of pulse crops including adzuki beans, chickpeas, cow peas, faba beans, field peas, lupins, mung beans, navy beans and pigeon peas. In all cases, there are two specific use patterns and application timings. The first is an early pre-emergent application for control of red legged earth mite (RLEM) and blue oat mite at rates of 175 – 350 g ai/ha. The approximate interval between application and harvest would range between 140 and 200 days, depending on the crop.

The second application is at a later stage of crop growth, at a maximum rate of 735 g ai/ha and is primarily for control of heliothis and other pests including loopers, corn earworms and green vegetable bugs. The withholding period for the later application is 28 days. Associated with the late stage application is a slaughter interval of 42 days for livestock that may be fed stubble, hay or fodder resulting from crops that have been treated with endosulfan. This slaughter interval is to allow any residues in animal commodities to fall below the domestic MRLs.

Australian data were generated for chickpeas, cow peas, faba beans, field peas, lupins and navy beans, as representatives of the pulse crop group. Trials were designed to reflect residues resulting from both use patterns, the early mite treatment and the late stage heliothis treatment. In many of the trials, four replicate samples were analysed separately, and these are individually tabulated to give an indication of the variation between replicate plots, especially in the trash/fodder samples.

Data that correspond to GAP (mite and heliothis treatment) are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Navy beans, Qld	735	41	0.031, 0.036, 0.046, 0.053
Navy beans, Qld	735	26 (1 spray)	0.012, 0.018
		26 (2 sprays)	<0.015, 0.040
		33 (2 sprays)	0.026, 0.051
Faba beans, NSW	350	196	<0.015, <0.015
	350 + 735	60	0.027, 0.028, 0.028, 0.1
Cow peas, Qld	735	28	0.30, 0.31, 0.32, 0.35
		35	0.16 (2), 0.22, 0.26
Cow peas, Qld	735	28	0.24, 0.27, 0.32, 0.35
		35	0.14 (2), 0.16, 0.19
Field peas	350	157	<0.015, <0.015
	350 + 735	49	0.006 (2), 0.007, 0.011
Lupins	350	203	<0.015, <0.015
	350 + 735	49	0.023, 0.055
Chickpeas	350	142	<0.015, 0.006
	350 + 735	38	0.12, 0.15, 0.20, 0.21
Navy bean trash/stubble	735	28	6.1, 12.7, 15, 16.1
Navy bean trash/stubble	735	26 (1 spray)	2.4, 6.3
		26 (2 sprays)	1.3, 1.8
		33 (2 sprays)	0.7, 1.4
Faba beans	350	196	0.034, 0.035
Cow pea trash/stubble	735	28	23, 29, 35, 37
		35	25, 30, 31, 46,
Cow peas trash/stubble	735	28	20, 25, 29, 47

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
		35	26 (2), 32, 33
Field pea forage	350	47	<0.1, <0.1
Field pea straw	350	157	0.035, 0.047
	350 + 735	49	0.32, 0.37, 0.40, 0.48
Lupin forage	350	61	<0.1, <0.1
Lupin straw	350	203	<0.1, <0.1
	350 + 735	49	0.19, 0.24
Chickpea forage	350	38	0.17, 0.22, 0.27, 0.29
Chickpea straw	350	157	0.06, 0.17
Chickpea straw	350 + 735	49	2.2, 4.3, 4.5, 9.4

LOD = 0.005 mg/kg in grain; LOQ = 0.1 mg/kg in grain, forage and straw

Residues in pulses are below the current temporary MRL of 1 mg/kg, with a 28 day withholding period. Although residues in cow peas at 28 days are above the primary feed commodities MRL of 0.3 mg/kg, current residues management advice indicates that a 42 day slaughter interval applies to livestock that may be fed treated pulses, therefore a feeding restraint for pulses is not required.

Residues in forage, stubble, straw and trash range from <0.1 to 47 mg/kg across the crop group. The current primary feed commodity MRL of 0.3 mg/kg is clearly exceeded for a number of those feed commodities. Applying an additional 42 days slaughter interval for livestock is only appropriate to those feed commodities in which residues are <2 ppm. The highest residues were found in cow pea fodder, where a slaughter interval of 70 days (on clean feed) would be required for livestock that would be exposed to fodder from treated crops.

As it is common agricultural practice to allow livestock to graze forage, straw and stubble of treated pulse crops, it is considered that a feeding restraint on product labels would be contrary to common practices. In addition, as a slaughter interval of 42 days on clean feed is not sufficient to allow endosulfan residues in animal commodities to fall below the current animal commodity MRLs, it is recommended that the late use pattern for control of heliothis and other pests (application at 735 g ai/ha with a 28 day withholding period) be deleted from all product labels. The early mite control treatment can be supported, and therefore on the basis of the data provided, residues in pulses are in rank order: 0.006 and <0.015 (7) mg/kg. An MRL of *0.1 mg/kg is recommended for pulses, with a nil withholding period for harvest.

Endosulfan residues in pulse forage (field peas, lupins and chickpeas) range from <0.1 to 0.29 mg/kg for samples taken at 38 to 61 days after treatment. The highest residues of 0.29 mg/kg dry weight were found in chickpea forage at 38 days after treatment. The data support an MRL of 0.3 mg/kg for pulse forage with a grazing withholding period of 49 days. This recommendation is made recognising that residues in forage should decline to below the current primary feed commodities MRL (0.3 mg/kg) within 49 days after treatment.

Endosulfan residues in pulse straw and stubble ranged from <0.1 mg/kg to 0.17 mg/kg for samples taken at harvest (157 to 203 days after treatment). An MRL of 0.3 mg/kg is recommended for pulse straw and fodder with a withholding period similar to that for harvest of the grain, i.e. nil.

3.2.12 Root and tuber vegetables

Current GAP for root and tuber vegetables (potato, carrot, beetroot, sweet potato, taro) allows application at 735 g ai/ha with withholding periods of 2 days for beetroot and 7 days for carrots, potatoes, sweet potatoes and taro. Taro is found on only two registered product labels[3].

[3] Thiodan EC Insecticide and Farmoz Endosulfan 350EC Insecticide.

The horticulture industry has requested that the withholding periods for all root and tuber vegetables be extended to 14 days.

Data that correspond to proposed GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Beetroot, Qld	735	14	0.20
Carrot, SA	735	14	0.06
Carrot, SA	735	14	0.095
Carrot, WA	735	14	0.037
Potato, Vic	735	14	<0.02
Potato, Qld	735	14	<0.02
Potato, WA	735	14	<0.02
Sweet potato, Qld	735	14	<0.02

Residues in root vegetables are in rank order: <0.02 (4), 0.037, 0.06, 0.095 and 0.2 mg/kg. An MRL of 0.5 mg/kg is recommended for root vegetables with a withholding period of 14 days for all root vegetables. The HRs for beetroot, carrot, potato and sweet potato are 0.2, 0.095, 0.02 and 0.02 mg/kg, respectively. An STMR of 0.028 mg/kg for the crop group is estimated for chronic intake purposes.

3.2.13 Stalk and stem vegetables

The current registered use pattern for celery is 66.5 g ai/100L with a withholding period of 2 days. This use is only found on one product label[4]. Australian data were provided for celery and rhubarb to allow consideration of a group MRL. The horticulture industry has requested withholding periods of 7 days for celery and rhubarb. As there is no use pattern for rhubarb, the proposed GAP only is considered.

The data that correspond to GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Celery, Qld	735	7	0.59
Celery, Vic	735	7	0.26
Rhubarb, Qld	735	7	0.059
Rhubarb, Qld	735	7	0.34

Residues in celery at 7 days after application are 0.26 and 0.59 mg/kg. These levels are below the temporary MRL of 2 mg/kg for stalk and stem vegetables.

The data that correspond to proposed GAP are in rank order: 0.059, 0.26, 0.34 and 0.59 mg/kg. The HRs for celery and rhubarb are 0.59 and 0.34 mg/kg, respectively. There are an insufficient number of data points to estimate an STMR for the group. On the basis of the data provided, an MRL of 1 mg/kg is recommended for stalk and stem vegetables with a withholding period of 7 days.

3.2.14 Cereal crops

Use of endosulfan on cereals includes two specific application timings, an early pre-emergent application for control of RLEM at 175 or 350 g ai/ha and applications at a later stage of crop growth for control of armyworm at 525 g ai/ha and heliothis at a rate of 735 g ai/ha. The use patterns for sorghum and maize differ from other cereal crops, as the only registered uses in these two crops are for heliothis control at 735 g ai/ha. The withholding period in all cases is 4 weeks for harvest.

[4] Nufarm Endosulfan 350EC Insecticide.

In the residue trials, samples from four replicate plots following two applications were analysed separately (as for pulses) and these are individually tabulated to give an indication of the variation between replicate plots, especially in the fodder/trash material. Data that correspond to GAP (heliothis control) for sorghum are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Sorghum, NSW	735	26	0.55, 0.78, 0.88, 1.1
		31	0.60, 0.66, 0.74, 0.94
Sorghum, NSW	735	29	0.42, 0.44, 0.56, 0.87
		35	0.27, 0.31 (2), 0.34
Sorghum, Qld	735	27	0.31, 0.37, 0.43, 0.44
		32	0.25, 0.34, 0.39, 0.51
Sorghum, NSW	735	27	1.5, 1.6, 1.7, 2.1
		34	0.88, 0.9, 1.0 (2)
Sorghum fodder/trash	735	26	30, 43, 55, 79
		31	22, 26, 39, 47
Sorghum fodder/trash	735	29	7, 15, 23, 31
		35	12, 13, 15, 21
Sorghum fodder/trash	735	27	5, 6 (2), 7
		32	3 (3), 5
Sorghum fodder/trash	735	27	47, 49, 55, 63
		34	16, 28, 36, 43

The data for sorghum can be extrapolated to maize; data for sorghum fodder can be extrapolated to maize and sweet corn fodder.

The registered uses of endosulfan on sorghum and maize are for control of heliothis, sorghum midge, sorghum head caterpillar and peach moth, and application timings are typically from head-emergence onwards. The data for sorghum clearly show that residues in grain at 28 days after application are greater than the current temporary MRL of 0.2 mg/kg for cereal grains. In the sorghum trials sampling intervals ranged from 26 to 51 days after application, and in the majority of the trials, residues in sorghum were above the temporary MRL for cereal grains and the primary feed commodities MRL, even at 51 days after application.

Registered labels offer contradictory advice with respect to sorghum and maize grain and corresponding fodder/stubble/trash. The residue management statements advise that a withholding period of 8 weeks would be required for grain used for livestock feed with a nil slaughter interval. However in the crop listing, sorghum, maize and other cereals may be harvested after 4 weeks for human consumption.

Residues in sorghum fodder range from 3 to 79 mg/kg in samples taken at 26 to 35 days after two applications. The data clearly show that residues far in excess of the primary feed commodity MRL of 0.3 mg/kg may be present in sorghum fodder at 4 to 5 weeks after application. If livestock were exposed to the highest level of 79 mg/kg, approximately 80 to 90 days on clean feed would be required for residues in meat (fat) to fall below the domestic MRL of 0.2 mg/kg. The interim recommendation for sorghum and maize fodder as part of the suspension of endosulfan products was:

- *Do Not Feed Treated Sorghum or Maize Fodder to Livestock; and*
- *If livestock have been fed treated sorghum or maize grain or fodder, animals must be kept on clean feed for at least 90 days before slaughter.*

As discussed above in section 2.11 (pulse crops), it is common practice to feed sorghum, maize and their crop parts to livestock; sorghum is predominantly grown for livestock feed. As a feeding restraint would be contrary to common livestock grazing and feeding practices and a slaughter interval of 90 days is considered impractical, the use patterns for sorghum and maize should be deleted from product labels.

Data that correspond to GAP for other cereal grains, except sorghum and maize are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Barley, Vic	350	158	0.008, 0.01
	350 + 735	42	0.66, 1.0, 1.1, 1.3
Barley, NSW	350	189	0.009, 0.05
	350 + 735	53	0.55, 0.46, 0.62, 0.72
Wheat, WA	350	203	<0.005 (2)
	350 + 735	49	<0.005 (2)
Wheat, NSW	350	130	<0.005 (2)
	350 + 735	35	<0.005, 0.046, 0.048, 0.099
Barley forage	350	70	0.079, 0.083
Barley straw	350	158	0.21, 0.22
Barley straw	350	158	0.1, 0.36
Barley straw	350 + 735	42	4.3, 5.1, 5.7, 6.4
Barley straw	350 + 735	42	1.6, 2.4, 2.9, 4
Wheat forage	350	61	<0.005 (2)
Wheat straw	350	203	<0.005, <0.005
Wheat straw	350	130	0.03, 0.03
Wheat straw/trash	350 + 735	49	0.24, 0.32
Wheat forage	350	55	0.25, 0.29
Wheat straw	350 + 735	35	0.39, 0.81, 1.4, 1.6

LOD = 0.005 mg/kg; LOQ = 0.1 mg/kg in grain, forage and straw.

The data for barley and wheat can be extrapolated to other cereal grains such as oats, rye and triticale. The withholding period for cereal grains is 28 days. The results show that residues in grain following the late application for heliothis control are greater than the current temporary MRL of 0.2 mg/kg at 28 days after application and are greater than the primary feed commodities MRL of 0.3 mg/kg. However, for the pre-emergent mite treatment, residues comply with the current MRL.

The residues management advice on registered labels is again contradictory in relation to cereal grains, and a withholding period of 4 weeks with a nil slaughter interval is indicated. The barley data indicate that a slaughter interval of up to 20 days on clean feed may be required for livestock that may be fed barley grain from treated crops.

Residues in barley and wheat straw/fodder (heliothis treatment rates) are greater than the primary animal feed commodities MRL of 0.3 mg/kg at intervals longer than 4 weeks. Label advice is required for livestock that are exposed to fodder or straw from treated crops. If animals were exposed to the highest levels of 6.4 mg/kg in barley straw, approximately 50 days on clean feed would be required for residues in fat to comply with the current animal commodity MRLs.

Residues data indicate that current use patterns (critical GAP heliothis control) for cereals require a slaughter interval for livestock in addition to the crop withholding periods, in order that the animal commodity MRLs are not violated. As it is common practice to feed cereal grains and their straw/hay to livestock, it is recommended that the late stage applications for heliothis control and other pests should be deleted from product labels. The use patterns that will remain are early pre-emergent applications for mite control. On the basis of that use pattern only, the temporary cereal grains MRL of 0.2 mg/kg may be amended to 0.1 mg/kg with a nil withholding period for harvest.

Residues in wheat and barley forage range from <0.1 mg/kg to 0.29 mg/kg at intervals of 55 to 70 days after treatment. On the basis of the data provided, a grazing withholding period of 10 weeks is recommended together with an MRL of 0.3 mg/kg for cereal forage. Residues in wheat and barley straw ranged from <0.1 to 0.36 mg/kg at intervals ranging 158 to 203 days after application. An MRL of 0.4 mg/kg is recommended for cereal straw and fodder, with a nil withholding period for harvest.

3.2.15 Tree nuts

Endosulfan is registered for use on cashews, macadamias, pecans and pistachios. The current use pattern is 52.5 g ai/100L or 525 g ai/ha and a withholding period of 14 days for the nuts mentioned above. The horticulture industry has requested that the withholding period for macadamias be reduced to 2 days.

Residues in macadamias at 2 days after application were <0.01 mg/kg in three trials conducted in NSW and Qld. The temporary MRL of 2 mg/kg adequately covers the current use patterns for cashews, macadamias, pecans and pistachios. On the basis of the data provided, an MRL of 0.05 mg/kg is recommended for tree nuts, with a withholding period of 2 days for macadamias and 14 days for cashews, pecans and pistachios.

3.2.16 Oilseeds

For oilseeds (canola, cotton, linseed, peanuts, soy beans, safflower, sunflowers), there are two specific application timings of endosulfan. One is an early pre-emergent application for control of RLEM and blue oat mite at rates of 175 – 350 g ai/ha and the other is application at a later stage of crop growth for heliothis control at rates of 735 g ai/ha. The withholding period for peanuts is 7 days, and 28 days for other oilseeds.

The use patterns for cotton and peanuts only include the late heliothis application, whereas for the other oilseed crops, both early and late applications are permitted.

For cotton, registered labels have a specific page entitled ‘Conditions of Use on Cotton’. In the conditions of use, application timings (aerial application) are limited to between 15 November to 15 January in NSW and 1 November to 31 December in Qld, with a maximum of 3 sprays at 735 g ai/ha. These timings would indicate that the period between final application and harvest would approximate 8 to 10 weeks.

The residue management section of product labels lists only cotton seed and meal (4 week withholding period with a nil slaughter interval for livestock), cotton trash and peanut hay . For cotton seed and meal, there is a direction that cotton trash must not be fed to livestock.

For peanut hay, there is a 7 day withholding period with a 42 day slaughter interval for livestock that may be fed treated hay. As data for peanuts and peanut hay were not provided to enable an assessment of the residues and trade situation, the uses should be deleted from all endosulfan product labels.

Data that correspond to GAP are summarised below:

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Canola	350	203	<0.005, <0.005
	350	211	<0.005, <0.005
	350	188	<0.005, <0.005
Cotton, NSW	735	27	0.007, 0.037, 0.047, 0.055
	735	41*	0.009, 0.029, 0.042, 0.080
Soya beans, Qld	735	28	0.018, 0.020, 0.033, 0.042
Sunflowers, NSW	735	29	0.12, 0.21, 0.28, 0.31
		34	0.16, 0.18, 0.23, 0.51
Canola forage	350	61	<0.005, <0.005
	350	47	0.23, 0.25
	350	98	0.09, 0.10, 0.11
	350	79	0.04, 0.05
Canola straw	350	203	0.006, 0.01

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
	350	211	0.008, <0.005
	350	188	0.05, 0.05
Cotton lint	735	27	0.069, 0.14, 0.19, 0.33
	735	41*	0.024, 0.066, 0.084, 0.10
Soya bean fodder/trash	735	28	1.5, 3.0, 3.2, 4.4
Sunflowers fodder/trash	735	29	9, 12, 13, 15
		34	39, 62, 59, 83

LOD = 0.005 mg/kg; LOQ = 0.1 mg/kg in seed, forage and straw/trash. * Closest interval in trials in relation to 'Conditions of use on cotton'.

In the canola trials, samples of seed and straw/trash were taken at 49 and 54 days after application at 735 g ai/ha, which do not strictly correspond to the critical GAP, therefore those data have not been included in the above table.

Endosulfan residues in cotton seed, soy beans and sunflowers were below the current temporary MRL of T1 mg/kg. The highest levels found were 0.51 mg/kg in sunflower seed.

Residues in fodder and trash of soy beans and sunflowers range from 1.5 to 83 mg/kg. As the levels clearly exceed the primary feed commodities MRL of 0.3 mg/kg, the following interim recommendation was made, noting there was no label direction in relation to feeding of oilseed fodders and trash:

- *Do Not Feed Fodder, Stubble or Trash from Treated Oilseeds (Canola, Cotton, Linseed, Peanuts, Safflower, Soya beans, Sunflowers) to Livestock*

The levels of endosulfan that are found in soybean fodder and sunflower trash would require a slaughter interval of greater than 42 days for any livestock that may have been fed treated commodities. As an interim measure, it was recommended that any livestock that may have been fed any oilseed fodder or trash must be kept on clean feed for 90 days before slaughter.

Cotton

In relation to cotton, registered labels have a specific page entitled 'Conditions of Use on Cotton'. In these conditions of use, application timings (aerial application) are limited to between 15 November to 15 January in NSW and 1 November to 31 December in Qld, with a maximum of 3 sprays at 735 g ai/ha. These timings would indicate that the period between final application and harvest would approximate 8 to 10 weeks, therefore the withholding period for cotton should be equivalent to 8 to 10 weeks. As of 4 January 2005, new conditions regarding the dates of application to cotton were published, where the dates for ground-based applications were set to match the existing dates for aerial application and the spray window extends from 1 October to 15 January for both NSW and Qld. Therefore the use pattern for cotton is determined by the application timings specified in the conditions of use.

For cotton, sampling in one trial was undertaken at 93 days and in another trial at 27, 41 and 80 days after application. As sampling in only one trial approximated the withholding period of 8 to 10 weeks, only one set of data from 41 days is included in the table below.

Commodity, Trial Site	Rate (g ai/ha)	WHP (days)	Total residues (mg/kg)
Cotton, Qld (2004)	735 (EC)	49	<0.02, <0.02
Cotton, Qld (2003/2004)			
	735 (EC)	49	<0.02, <0.02
Cotton, NSW (2003/2004)			
	735 (EC)	48/49	<0.02, <0.02
Cotton, NSW (2003/2004)			
	735 (EC)	49	<0.02, <0.02
Cotton, NSW 1999	735 (EC)	41*	0.009, 0.029, 0.042, 0.080

* Closest interval in trials in relation to 'Conditions of use on cotton'.

Residues in cotton fodder are not tabulated, as the control samples in one relevant trial were contaminated, therefore the data must be interpreted with care. The levels of endosulfan in cotton fodder ranged 1 to 12 mg/kg, at intervals of 27 and 41 days after application.

As feeding of cotton fodder, stubble and trash is not considered to be Good Agricultural Practice (GAP), the following feeding restraint was re-emphasised as part of the 1998 interim recommendations for the endosulfan review:

- *Do Not Feed Cotton Forage, Stubble, or Trash to Livestock*

The use of endosulfan for cotton production has previously been linked to residues in beef, for example, from spray-drift, contaminated feed and poor management practice. However, significant measures have been put in place by the APVMA and the cotton industry aimed at preventing endosulfan contamination in meat commodities, with a high level of success.

Never-the-less, the risk of residues in trade for the meat industry remains from the feeding of cotton fodder, stubble and trash, particularly in drought situations.

In assessing the use of endosulfan in cotton, two alternative approaches were considered:

1. continue to permit the use of endosulfan on cotton, with the following label restraint:
   - **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**
2. delete the uses of endosulfan on cotton.

These options are discussed more fully in section 3.2.21.

The oilseeds data (as with pulses and cereals) indicate that endosulfan residues in fodder, straw and trash following application at 735 g ai/ha (heliothis control) were clearly greater than the primary feed commodity MRL of 0.3 mg/kg and slaughter intervals ranging 20 to 90 days on clean feed would be required if livestock were exposed to such levels for prolonged periods. As a 90 day slaughter interval is not considered to be practical, it is recommended that the late stage application for heliothis control (735 g ai/ha) be deleted from product labels for oilseeds (except cotton).

The current temporary MRL of 1 mg/kg is appropriate for the remaining uses on oilseeds, which include mite treatment only. A nil withholding period for harvest is recommended in relation to the above MRL for canola, linseed, soybeans, safflower and sunflowers. For cotton, the withholding period is 8 weeks. As the oilseed MRL of 1 mg/kg will also accommodate the existing cotton seed oil MRL of T0.5 mg/kg, the oil MRL is not required.

Forage data were generated for canola only, at the timings and rates applicable for mite control. Residues ranged <0.1 to 0.25 mg/kg at intervals of 47 to 79 days after application. On the basis of the canola forage data, an MRL of 0.3 mg/kg is recommended for oilseed forage with a grazing

withholding period of 8 weeks. This should allow sufficient time for residues in other oilseed forages to decline to below the maximum feed level of 0.3 mg/kg.

Similarly with straw and fodder of oilseeds, data for canola were generated at the 350 g ai/ha rate and mite application timings. On the basis of the data provided an MRL of *0.1 mg/kg is recommended for oilseed straw and fodder with a nil withholding period for harvest/grazing.

The majority of submissions received during the consultation period supported of option 1 for use of endosulfan on cotton (see above), with a revised restraint statement for feeding of cotton trash and remaining crop by-products after harvest. On that basis, the oilseed MRL of 1 mg/kg will adequately accommodate residues in cotton seed, with a withholding period of 8 weeks as determined by application dates and timings. As the oilseed MRL will also accommodate residues in cotton seed oil, the existing cotton seed oil MRL of T0.5 mg/kg is not required. The following feeding restraint is recommended:

Do Not Feed Cotton Fodder, Stubble or Trash to Livestock

3.2.17 Pastures and related crops

Use patterns for clover and medic seed crops, lucerne seed crops, pastures, chou moeiller and vetch are found on a number of product labels. Residues data for pastures were requested as part of the interim regulatory action in 1998, however no new data were generated.

In the 1998 APVMA review of endosulfan, data from the 1989 JMPR were evaluated against registered use patterns[5]. The data were from single applications ranging from 210 to 530 g ai/ha or 0.3 to 0.7× the maximum application rate in Australia. As the data did not correspond to GAP in Australia, additional data were requested.

As new data supporting the existing use patterns have not been provided, the APVMA cannot be satisfied that pastures and related crops will not contain residues at unacceptable levels. Therefore, it is recommended that all use patterns relating to control of pests on pastures, clover and medic crops, lucerne, chou moeiller and vetch must be deleted from all registered labels.

3.2.18 Animal feed commodities and animal commodity MRLs

A list of animal feed commodities and residues therein is given in Table 1. The data are taken from residue trials described in section 8.

Table 1: Livestock dietary burden estimates from Australian residues data (Cattle)

Commodity	HR/STMR-P (mg/kg)	Livestock diet (%)	Residues in feed (ppm)
Citrus pulp	0.45①	20	0.09
Apple pomace	0.64	20	0.13
Pulses	0.016	100	0.016
Pulse forages	0.29	100	0.29
Pulse straw/fodder	0.17	100	0.17
Cereal grains	0.015	100	0.015
Cereal forage	0.29	100	0.29
Cereal straw/fodder	0.36	100	0.36
Oilseed forage	0.25	100	0.25
Oilseed straw/fodder	0.05	100	0.05

① PF × STMR in residue trials.

[5] Page 55 of the APVMA Review of Endosulfan.

It should be noted that residues data were generated for representatives of particular crop groupings, therefore there are other feed commodities from related crops for which data were not provided, but for which valid extrapolation can be made. For example, the data for sorghum fodder can be extrapolated to maize and sweet corn fodder. Similarly, the data for navy beans and cow peas can be extrapolated to other pulse crops such as mung beans, faba beans, field peas, chickpeas, lupins, adzuki beans and pigeon peas. The sunflower data can be extrapolated to safflower and the data for sunflower and canola can be extrapolated to linseed. Similarly the barley straw data can be extrapolated to wheat, oats, rye and triticale.

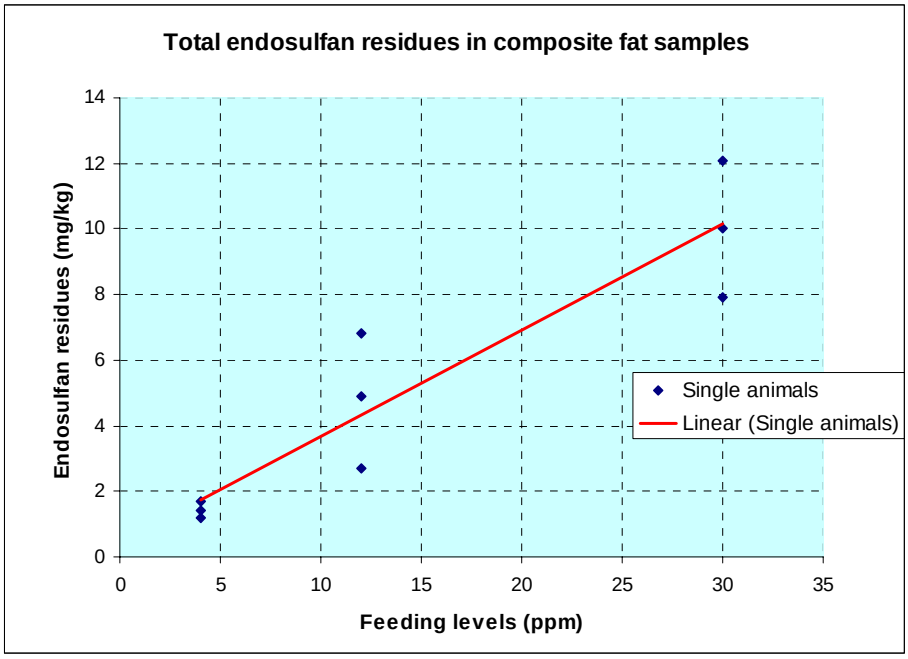
The current animal commodity MRLs of T0.2 mg/kg in edible offal, 0.2 mg/kg in meat (mammalian)[in the fat] and T0.5 mg/kg in milk (in the fat) are based on a maximum feed level of 0.3 ppm[6]. Existing labels included crop harvest and grazing withholding periods, together with a 42 day slaughter interval for livestock that may graze or be fed a number of commodities treated with endosulfan (see section 8**).** This withhold from slaughter period was to allow residues in livestock (specifically fat) to decline to below the domestic MRL.

With the deletion of late stage applications in broadacre crops except cotton (specifically application at 735 g ai/ha with a 28 day withholding period), the dietary burden table is significantly different to that previously considered in the interim report. The greatest exposure to grazing livestock is from cereal straw and fodder, following application for mite control.

For all feed commodities considered, the exposures approach the maximum feed level of 0.3 mg/kg, with levels ranging from 0.015 to 0.36 mg/kg. However, on the basis of the estimates presented in the dietary burden table, a maximum feed level of 0.4 mg/kg is appropriate. Following dosing for 28 days at a feed level of 4 ppm, maximum residues of 0.07 mg/kg in muscle, 1.7 mg/kg in composite fat, 0.98 mg/kg in liver, 0.08 mg/kg in kidney and 0.08 mg/kg in whole milk, were found. The mean levels (n = 3) of total endosulfan were 0.04 mg/kg in muscle, 1.4 mg/kg in composite fat, 0.7 mg/kg in liver, 0.07 mg/kg in kidney and 0.07 mg/kg in whole milk. The scatter of results for composite fat is shown in figure 3.1.

[6]*The NRA review of Endosulfan (Aug 1998)*; Agricultural Assessment. Prelim report *Endosulfan Uptake Study* 1996.

Figure 3.1.



At higher feed levels, the scatter or variation observed between single animals is greater than that found at the lowest feed level of 4 ppm.

Scaling the residues in fat (highest single animal result) for exposure at a level of 0.4 ppm, residues of 0.17 mg/kg would be expected. This is still within the current MRL of 0.2 mg/kg for meat (mammalian)[in the fat]. Applying the same principle to muscle and edible offal, residues of 0.1 and 0.008 mg/kg are estimated for liver and kidney, respectively, and 0.007 for muscle. It is recommended that the current temporary MRL of 0.2 mg/kg for edible offal (mammalian) be made a permanent MRL.

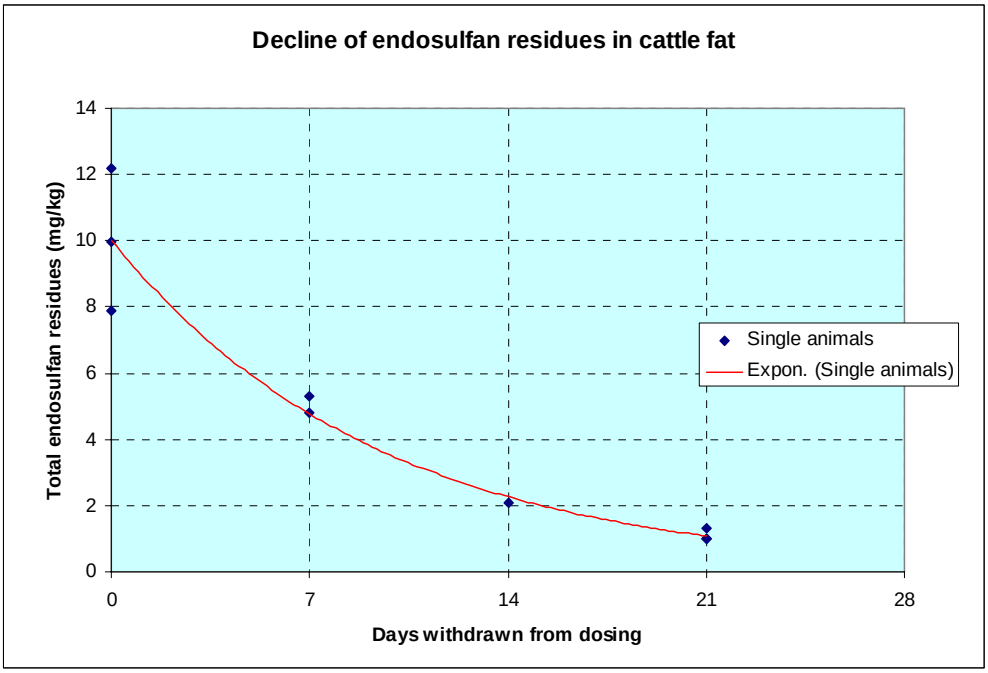
Maximum residues of 0.08 mg/kg were present in whole milk following dosing at 4 ppm for 28 days, which is scaled to 0.008 mg/kg for a maximum feed level of 0.4 mg/kg. After 7 days of dosing, total endosulfan levels appeared to plateau in milk, with an occasional spike at a later sampling point (see section 4.2.1). On the basis of the data for milk, the current temporary entry of 0.5 mg/kg for milk [in the fat] should be amended to 0.02 mg/kg for whole milk.

Residues were determined in cream following dosing at 12 ppm for 9 days, with levels ranging from 0.81 to 1.42 mg/kg. Maximum endosulfan residues in milk following dosing at 12 ppm were 0.22 mg/kg. A mean concentration factor of 4.7 is estimated from these results.

Depuration of residues in muscle, fat, liver and kidney were determined as part of the cattle transfer study. The depletion of endosulfan residues in fat is shown in figure 3.2.

Using the depuration data from the transfer study in dairy cattle (section 9**),** a half-life of 7 days is calculated in fat. It should be noted however, that the fat samples in the transfer study were analysed as a composite (subcutaneous, omental and perirenal) and therefore the time taken to deplete in individual fat depots cannot be ascertained. Due to differences in individual fat depots and to allow for variation in animals, a half-life of 10 days is considered to be appropriate.

Figure 3.2.



On the basis of a depuration half-life of 10 days and to reach a target of 0.1 mg/kg (Codex MRL) in meat [fat] from the current MRL of 0.2 mg/kg, an Export Slaughter Interval (ESI) of 21 days on clean feed is recommended to meet export trade markets.

For poultry, a conservative maximum feed level (MFL) of 0.2 ppm is estimated from residues present in oilseeds, cereal grains and pulses. In the poultry metabolism study provided (section 3.1), hens were dosed orally for 12 days at levels ranging 10 to 12 ppm in the feed. Scaling the radioactive residues present for a maximum feed level of 0.2 ppm, endosulfan residues (α- and β-endosulfan and endosulfan sulfate) of 0.016 and 0.014 mg/kg would be present in fat, 0.008 mg/kg would be present in skin, 0.008 mg/kg would be present in eggs and 0.003 mg/kg would be present in liver. On the basis of the metabolism study, MRLs of 0.02 mg/kg, 0.05 mg/kg and *0.01 mg/kg are recommended for eggs, poultry meat [in the fat] and poultry offal.

3.2.19 Processing and storage stability

Storage stability data are described in section 8 for both crop and animal matrices. The residues data provided for crops and animal commodities are adequately covered by the storage intervals in the stability studies and therefore the reported residues in supervised trials reflect residues found after treatment.

Processing data were provided as part of the residues studies. These are described in the individual studies in section 8**.**

3.2.20 Trade considerations

The following export data were extracted from *Australian Commodity Statistics 2004*, published by the Australian Bureau of Agriculture and Resource Economics, Canberra.

Australian exports of sheep meat were on average 163 kt mutton and 91 kt lamb per year over the period 1996 – 2003 and were valued up to $600,000,000 per annum Australia's main export markets for sheep meat in 2003 are shown in the following table.

Export Destination	Export Value ($m)	
	Mutton	Lamb
Saudi Arabia	65	
USA	67.9	257.5
Chinese Taipei	32.2	
South Africa	11.1	2.1
Japan	29.9	42.3
Singapore	20.4	
Malaysia	15.9	
EU	27.4	92.4
Papua New Guinea	6.1	14.4
Canada	3.6	
Republic of Korea	2.2	
UAE		29.9
Other (unspecified)	92.4	162.4

Australian exports of beef and veal have averaged $3.2bn over the period 1996 – 2003, with up to $4.3bn in 2001. The main export markets for beef and veal reported in 2003 are tabulated below:

Export Destination	Export Value ($m)
Japan	1384.4
USA	1332.3
Republic of Korea	250.7
Chinese Taipei	126.7
Canada	110.9
Malaysia – Singapore	86.8
EU	49.2
Indonesia	38.4
Oceania (NZ, PNG, South Pacific Islands)	26.2
Middle East (Saudi Arabia, UAE, Kuwait)	25.4
Philippines	23
Hong Kong, China	15

Australia exports large quantities of cereal grains, with exports of wheat and flour valued at up to $3.4bn in 2003-2004 and up to $4.6bn in 2001 – 2002. The main markets for Australian wheat and flour are the Middle East (Iraq, Kuwait, UAE, Yemen), Asia (Indonesia, Japan, Republic of Korea, Malaysia) and Africa (Egypt, South Africa and Ethiopia). Main markets for grains other than wheat could not be determined.

Cottonseed, cottonseed oil and cottonseed meal are also exported by Australia. Whilst specific data for cotton seed meal were not available, average exports of cotton seed and cotton seed oil over the period 1996 – 2004 averaged 384 kt and 1.36 kt, respectively. The major export destinations for cotton seed are Japan and the Republic of Korea, at 134 and 28 kt, respectively in 2003 – 2004; the values of the export markets were not reported.

MRLs have been set for endosulfan in cereal grains, cotton seed and cattle and sheep commodities in most countries worldwide and by Codex. These are tabulated below:

Australian Pesticides and Veterinary Medicines Authority (APVMA)

Commodity	Endosulfan MRL (mg/kg)						
	Australia①	Codex	USA	Japan②	Korea	EU	Taiwan
Meat (mammalian) [in the fat]	0.2	0.1 (fat)	0.2 (cattle fat)	0.1	0.1	0.1 (meat & fat)	0.1 (fat)
Edible offal	0.2	–	0.2	0.2	–	0.1	–
Milk	0.02	0.004 F③	0.5 (fat)	0.004③	0.1	0.004③	0.004 F
Cereal grains	0.1	–	–	0.1	0.1	–	–
Wheat grain	0.1	0.2	0.1	0.2	0.1	0.05	–
Cotton seed	1	1	1	1	–	0.3	–

① Proposed MRL ② Provisional MRL listing. ③Based on CCPR policy the figure of 0.004 mg/kg F is equivalent to 0.1 mg/kg in milk fat. The figures reported for Japan and EU do not make the clear distinction of **F** and therefore the value could be misinterpreted. A comparison of the milk MRLs for different countries requires conversion of the values to milk [in the fat], i.e. multiply the Codex CXL by 25.

Cereal Grains: The main markets for wheat are the Middle East and Asia, and there appear to be no MRLs set for these countries. The proposed Codex MRL for wheat is higher than that proposed for Australia. There should be no prejudice to trade for wheat exports, once the proposed MRL is established, as most of the major markets accept Codex MRL for trade.

Cottonseed: The Australian MRL for cotton seed is included in the oilseed MRL of 1 mg/kg, which is the same as that of Codex, Japan and the USA. The current crude cottonseed oil MRL is the same as that of Codex. However it will be deleted, as residues in oil will be accommodated by the oilseed MRL. Trade in the past has not been prejudiced by the presence of these MRLs for endosulfan and this is not expected to alter in the future, due to the provisional MRLs for endosulfan proposed by Japan.

Cattle and Sheep: The Australian MRL for meat fat is twice that of the Codex value. Australia's main markets are in North America, Asia and the Middle East. Most Asian countries that have not established MRLs for endosulfan in meat commodities adopt either the Codex value or the EU value of 0.1 mg/kg. There have been past incidents in Asia particularly when shipments of meat have been rejected for exceeding the Codex MRL and this difference could be seen to prejudice Australia's trade to these markets. To overcome this problem, an Export Slaughter Interval of 21 days is recommended for any livestock that have been exposed to endosulfan residues in feeds.

Export trade in meat is drawn from both grazed animals and from cattle in feedlots situations. The source of endosulfan residues could be from forage crops or supplementary feeds, which include treated crops and crop by-products. Silage, cut fodder and hays could also be sources of endosulfan for export animals. Animal feed commodities that result in residues above 0.4 mg/kg endosulfan (the proposed Maximum Feed Level) should be restricted from feeding to cattle and sheep. With significantly amended use patterns and the corresponding Export Slaughter Interval, residues in meat fat should not exceed the established Codex MRL of 0.1 mg/kg.

3.2.21 Meat trade implications from Animal feed commodities

A number of broadacre crops for which endosulfan is registered are used as animal feed commodities, potentially resulting in endosulfan meat residue violations.

For those crops grown primarily or substantially for livestock feed the APVMA has determined that some endosulfan uses will no longer be permitted, where they present an undue risk to trade and alternative risk mitigation measures are unlikely to be complied with. This includes some uses for cereal crops, oil seed crops (except cotton and peanuts) and pulse crops.

Cotton and legume vegetables are not grown primarily for feed purposes. The feeding of cotton fodder, stubble and trash to livestock is known to occur and has the potential to result in endosulfan

residues in meat. It is also not considered to be GAP. Historically, cotton production has previously been responsible for endosulfan residues in beef because of contaminated feeds, spray drift and other poor management practices.

A key issue from the Draft Review Report was the continued use of endosulfan on cotton and legume vegetables. In assessing these uses, two alternative approaches were considered:

1. continue to permit these uses with the following label restraint:

- **This Product Must Not Be Used On Crops That Will Or May Be Fed To Livestock.**

2. delete these uses because of the risk of violative residues in meat.

The APVMA sought assurances that, were uses for cotton and legume vegetables to be retained, appropriate and effective safeguards could and would be put in place to protect against violative residues in meat, and so protect Australia's meat trade.

During the public consultation period submissions were received with support for both of these uses. Additionally submissions were received which did not support the continued use on legume vegetables.

An industry commitment was received from the Australian cotton industry and the livestock industry regarding continued use of endosulfan in cotton. Specifically Cotton Australia and the Cotton Ginners Association have agreed an MOU with the Cattle Council of Australia and the Australian Feedlotters Association that specifies the management practises to be adopted by cotton growers and livestock producers to allow the continued use of endosulfan in cotton. This MOU and associated Best Management Practices and Codes of Practice, have enabled the APVMA to be satisfied with regard to the risks of residue contamination in meat destined for the domestic or trade market. (Attachment 1 contains a copy of the MOU). Endosulfan residues in meat of livestock will continue to be monitored by the National Residues Survey monitoring as is currently the case, and the work of the "Endosulfan Task Force" administered through the Beef Industry Advisory Committee (BIAC), and the SAFEMEAT Committee under the Department of Agriculture Fisheries and Forestry will also continue.

The public comment period elicited few responses from representatives in the horticultural industry.

Continued use of endosulfan in legume vegetables is likely to cause exposure to livestock from feeding of pea and bean vines and hay containing endosulfan residues at levels that are unacceptable in relation to existing animal commodity MRLs.

Legume vegetables are not grown primarily for livestock feed. However, the by-products from these crops e.g. hay, are actively sought after as valuable livestock feeds, particularly in time of drought. These by-products are not always consumed on farm but can be on-sold to third parties for use in processed animal feeds and/or fed directly to livestock.

The horticultural industry is not as well organized as the cotton industry. It is a highly fragmented and diverse group, comprising large numbers of small producers, many from non-English speaking backgrounds, spread over a wide geographical area. In contrast to the cotton industry, the horticultural industry does not have in place adequate mechanisms to managed residues at this time e.g. commodity vendor declarations, BMPs or MOUs. The industry is slowly adopting the use of vendor declarations, but not to any large extent at this time. The response from the horticultural industry noted their inability to control the actions of third parties in respect to the management of residues in livestock.

3.2.22 Dietary exposure

The ADI and ARfD for endosulfan are 0.006 and 0.02 mg/kg bodyweight/day, respectively. At the time of publication of the 1998 Endosulfan interim report the National Estimated Daily Intake (NEDI) was equivalent to 339% of the ADI. This estimate was based on temporary MRLs and used available refinements. It is recognised that the NEDI is a conservative estimate of chronic exposure and that excursions above the ADI may be allowed (Residues Appendix 4). Using the supplementary residues data that have been submitted, the NEDI is now equivalent to 27% of the ADI.

The ARfD for endosulfan was set by the TGA in December 2000. The dose is 0.02 mg/kg bodyweight, based on a NOEL of 2 mg/kg bodyweight/day and a 100-fold safety factor from a developmental study in rats. The LOEL was 6 mg/kg bodyweight/day.

In 1998, at the time of publication of the endosulfan review, acute or short-term dietary exposures were not routinely considered in Australia, as the methodology was still under development[7]. The National Estimated Short Term Intake (NESTI, Residues Appendix 2) is calculated using the supplementary residues data corresponding to registered use patterns. For the 2 to 6 year subpopulation, the acute reference dose was exceeded for pears (3.6-fold), leafy vegetables (20 to 27 fold) and Brussels sprouts (1.3 fold). For the 2 years + group (general population), the acute reference dose was exceeded for leafy vegetables (17 to 20-fold); pears approach the acute reference dose.

Short-term dietary intake must not exceed the acute reference dose. To reduce the exposure from residues in pears, the interim regulatory action recommended extension of the withholding period from 14 days to 28 days, to allow residues to decline to acceptable levels:

In addition, the suspension of endosulfan products no longer allow use on leafy vegetables or brussels sprouts. Labels contain a statement to this effect.

The revised short-term dietary exposure ranges from 0 to 82% of the acute RfD for the 2 to 6 years age group and from 0.1 to 71% of the acute RfD for the 2 years and above age group (see Residues Appendix 4, technical report).

3.3 CONCLUSIONS FROM RESIDUES ASSESSMENT

The following conclusions were determined following assessment of the residues data. (These conclusions are further considered in conjunction with OHS conclusions in formulating the final review outcomes, shown in section 7).

3.3.1 Use pattern variations

Residues data not provided

For the following crops, residues data were required but were not provided to the APVMA.

- bananas;
- berries and other related fruit such as grapes and currants;
- bulb vegetables, namely onions and shallots;
- pastures, chou moeiller, vetch, lucerne, clover and medic crops; and
- peanuts.

[7] JMPR first reported short-term estimates of dietary intake in 1999.

On this basis the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people using anything containing its residues and have been deleted:

Short-term dietary concerns were highlighted

For the following crops short-term dietary concerns were highlighted.

- leafy vegetables, silverbeet, spinach and cole crops (except broccoli, cabbage (head) and cauliflower); and
- Brussels sprouts.

On this basis the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people using anything containing its residues and have been deleted:

Crops produced primarily or substantially for livestock feed

For the following crops, that are produced either for livestock feed only or are grown and used for human food and for livestock feed, risks from residues in trade were shown to be unacceptable.

- the control of heliothis and other pests at the rate of 735 g ai/ha (2.1 L product/ha) in pulse crops, cereal crops and oilseed crops (except cotton). This includes the use patterns for, maize and sorghum.
- The use pattern for sweet corn .

On this basis the APVMA cannot be satisfied that the continued use of endosulfan for these uses would not unduly prejudice trade or commerce between Australia and places outside Australia, and have been deleted:

Crops produced primarily for purposes other than livestock feed

The following crops are produced primarily for purposes other than livestock feed:

- legume vegetables (green beans and green peas);
- cotton.

The current use of endosulfan in legume vegetables will be deleted due to ongoing concerns that the likely exposure to livestock from feeding of pea and bean vines and hay may be at levels that are unacceptable in relation to existing animal commodity MRLs. As a feeding restraint would be contrary to common livestock grazing and feeding practices, the APVMA has concluded that the use patterns for green beans and peas will be deleted from product labels.

Uses on cotton will be retained, as discussed in section 3.2.21.

3.3.2 New label instructions

In addition to the labelling requirements as defined in the Agvet Labelling Code (2001) and the interim report for the review of endosulfan (1998), the following instructions have been included on all product labels included in this review. Products which are subject to the outcomes of the review will have there labels varied in the same way.

Livestock feeding restraints:

- This product must not be used on cotton where cotton trash, fodder or stubble (excluding seed and hulls) will or may be fed to livestock.
- Do Not Feed Cotton Fodder, Stubble or Trash To Livestock
- Do Not Feed Vegetable Wastes or Wrapper Leaves of Treated Vegetable Crops to Livestock
- Do Not Feed Treated Melons or Melons Crops To Livestock

- Do Not Feed Treated Tomato Crops To Livestock

Livestock Destined for Export Markets
The label withholding periods for grazing only apply to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that the Export Slaughter Interval (ESI) is observed before stock are sold or slaughtered.

Export Slaughter Interval (ESI) – 21 days
Livestock that have been grazing on or fed treated crops (Except for label exclusions – cotton, melons, tomato, vegetable wastes/wrapper leaves) should be placed on clean feed for 21 days prior to export slaughter.

3.3.3 Withholding periods

The following withholding period statements have been included on product labels in relation to the above MRLs:

Citrus fruit:	Do Not Harvest For 3 Days After Application
Pome fruit	Do Not Harvest For 28 Days After Application
Avocado, Kiwifruit, Mammey, Passionfruit, Pomegranate, Sapodilla:	Do Not Harvest For 14 Days After Application
Custard Apple, Guava, Lychees, Longans, Mango, Pawpaw, Persimmon, Rambutan, Tamarillo:	Do Not Harvest For 7 Days After Application
Broccoli, Cabbage, Cauliflower:	Do Not Harvest For 7 Days After Application
Cucurbits:	Do Not Harvest For 3 Days After Application
Capsicum, Tomatoes:	Do Not Harvest For 3 Days After Application
Cape gooseberry, Eggplant, Okra	Do Not Harvest For 7 Days After Application
Beetroot, Carrot, Potato, Sweet Potato, Taro	Do Not Harvest For 14 Days After Application
Celery, Rhubarb	Do Not Harvest For 7 Days After Application
Cashews, Pecans, Pistachios	Do Not Harvest For 14 Days After Application
Macadamias	Do Not Harvest For 2 Days After Application

	Harvest	**Grazing**
Pulse Crops (Adzuki beans, Chickpeas, Cow peas, Faba beans, Field peas, Lentils, Lupins, Mung beans, Navy beans, Pigeon peas)	Nil	Do Not Graze Or Cut For Stockfood For 7 Weeks After Application.
Cereals (Barley, Oats, Rye, Triticale, Wheat)	Nil	Do Not Graze Or Cut For Stockfood For 10 Weeks After

		Application
Oilseeds: Canola (Rapeseed), Linseed, Soya beans, Safflower, Sunflowers): Harvest: Nil; Grazing	Nil	Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Cotton	Do Not Harvest For 8 Weeks After Application	

3.3.4 MRLs

The following amendments to the MRL Standard will been made:

Table 1

Endosulfan

Code	Food	MRL (mg/kg)	
		Delete	Add
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2	–
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2	2
FB 0018	Berries and other small fruits	T2	–
VB 0400	Broccoli	T2	1
VB 0041	Cabbages, head	T2	1
VB 0404	Cauliflower	T2	1
GC 0080	Cereal grains	T0.2	0.1
FC 0001	Citrus fruits	T2	0.3
OC 0691	Cotton seed oil, crude	T0.5	–
MO 0105	Edible offal (mammalian)	T0.2	0.2
PE 0112	Eggs	T*0.05	0.02
VC 0045	Fruiting vegetables, cucurbits	T2	0.1
VO 0050	Fruiting vegetables, other than cucurbits	T2	1
MM0095	Meat (mammalian) [in the fat]	0.2	0.2
ML 0106	Milks [in the fat]	T0.5	–
ML 0106	Milks	–	0.02
SO 0088	Oilseed	T1	1
VA 0385	Onion, bulb	T0.2	–
FP 0009	Pome fruits	T2	1
PO 0111	Poultry, edible offal of	0.2	*0.01
PM 0110	Poultry meat [in the fat]	0.2	0.05
VD 0070	Pulses	T1	*0.1
GC 0649	Rice	T0.1	–
VR 0075	Root and tuber vegetables	T2	0.5
VA 0388	Shallots	T2	–
VS 0078	Stalk and stem vegetables	T2	1
FS 0012	Stone fruits	T2	–
DT 1114	Tea, Green, Black	T30	–
TN 0085	Tree nuts	T2	0.05

Table 4

Code	Animal Feed Commodity	MRL (mg/kg)	
		Delete	Add
-	Primary Feed Commodities	0.3	–
AB 0226	Apple pomace, dry	–	1

-	Cereal forage (green)	–	0.3
-	Citrus pulp and pomace, dry	–	2
-	Forage of pulse crops (green)	–	0.3
-	Forage of oilseed crops	–	0.3
AS 0081	Straw and fodder (dry) of cereal grains	–	0.4
-	Straw and fodder (dry) of oilseeds	–	*0.1
-	Straw and fodder (dry) of pulse crops		0.3

3.3.5 Outcome

The residues evaluation found that the APVMA could not be satisfied that use of products containing endosulfan 350 g/L in EC formulations would not be an undue hazard to the safety of people using anything containing its residues, and would not unduly prejudice trade or commerce between Australia and places outside Australia. The evaluation concludes that instructions on product labels be varied by deleting:

- uses where no data were provided to support them;
- uses where short-term dietary concerns were highlighted;
- late season use for the control of heliothis and other pests at the rate of 735 g ai/ha (2.1 L product/ha) in pulse crops, cereal crops and oilseed crops (except cotton)
- maize, sorghum and sweet corn; and
- legume vegetables (green beans and green peas).

Labels have been varied as was proposed, and the APVMA is satisfied that continued use and other dealings of products containing endosulfan 350 g/L in EC formulations would not be an undue hazard to the safety of people using anything containing its residues, and would not unduly prejudice trade or commerce between Australia and places outside Australia.

4. OH&S WORKER EXPOSURE ASSESSMENT SUMMARY

4.1 INTRODUCTION

The 1998 APVMA interim report of the review of endosulfan raised concerns, with regard to exposure for workers during certain use and re-entry activities. The OH&S risk assessment at this time was largely carried out using surrogate exposure data due to a lack of suitable exposure data.

The interim report noted that the major use of endosulfan in Australia, at that time, was in cotton production, representing approximately 70% of use, and vegetables, accounting for 20%, with the remaining 10% divided between oilseeds, pome and stone fruits, exotic fruits and other crops, such as pulses and ornamentals. Label instructions permit the use of endosulfan in cereal crops, tobacco, and nursery crops. Current labels include instructions for application by ground and by air, with endosulfan being applied aerially in significant quantities since the major crop is cotton. Ground applications are either by boom spray, airblast, airshear or knapsack with hand wand/nozzle. Endosulfan was noted to be an integrated pest management (IPM) tool in both horticulture and broadacre crops.

Information available at the time of the interim report indicated that workers involved in crop tending and harvest activities could become contaminated with endosulfan product residues. Poisoning incidents reported overseas indicated that field workers may also experience health effects when re-entering endosulfan treated areas and it was identified that re-entry restrictions are needed on current endosulfan product labels.

Consequently, the APVMA decided that certain uses of endosulfan should continue on a temporary basis until additional worker exposure data were obtained. An interim re-entry period of 2 days (for field and orchard crops and for greenhouses) was recommended until new Australian data was generated. Existing guidance on safe flagging procedures was also identified for upgrading.

Due to the apparent lack of suitable studies (available in Australia or overseas) the APVMA required worker exposure data to be generated under actual Australian use conditions in order to determine the extent and circumstances of exposure to endosulfan in occupational settings. Work practices that were identified by the APVMA for further assessment were:

- Mixer/loaders in ground and aerial applications
- Manual flaggers for aerial applicators
- Orchard ground spray applicators (including re-entry)
- Broadacre ground spray applicators (including re-entry)
- Greenhouse workers
- Workers using hand-directed spray applicators.

The requisite worker exposure studies were conducted by the Australian Centre for Agricultural Health and Safety (Moree) and the Centre for Pesticide Application Safety (Gatton). The studies were based on a protocol approved by the APVMA and NOHSC, and in accordance with standards prescribed by the New England Health Research and University of Sydney Research ethics committees. All studies used the same formulation of endosulfan containing 350 g ai/L, which was considered representative of each of the products under review.

4.1.1 Dermal absorption factor for exposure to concentrates and spray mixtures

The endosulfan draft report (OH&S component report) used a dermal absorption factor of 10%, which was derived from a new *in vitro* dermal absorption study (Davies, 2002) submitted in late 2003. During the public consultation phase, the appropriateness of the dermal absorption factor (10%) used in the OHS risk assessment was questioned as well as the use of cotton dislodgeable foliar residue (DFR) data to determine re-entry intervals for other broadacre and tree crops. Additional re-entry studies on melons, peaches and grapes (Singer, 1995) were submitted for consideration as part of the public consultation (see section 4.2.4 re-entry exposure).

From further consideration of these submitted studies (Refer to volume two of this report for the technical assessment of these studies), it is apparent that endosulfan is less well absorbed across rat skin *in vivo* than *in vitro*. Under identical experimental conditions, human epidermis is at least 30-fold less permeable to endosulfan than rat epidermis.

In light of these new findings the previous worker exposure estimates where dermal absorption figures were derived from animal experimentation results and applied to human exposure scenarios were revisited. A dermal absorption factor of 0.5% for concentrates i.e. mixing/loading, and 1.52% for spraying and re-entry activities has been used in the OHS risk assessment.

Consistent with the EC Guidance Document on Dermal Absorption, factors for endosulfan can be calculated by adjusting the rat *in vivo* absorption values by the ratio of the human to the rat *in vitro* absorption. The dermal absorption factor for concentrate exposure will be 20% x 0.025 = 0.50%, while the factor for exposure to spray mixture will be 46% x 0.033 = 1.52%.

4.2 FINDINGS

The revised dermal absorption values and re-entry studies have revised the findings in the Draft Review report. They are reflected in all conclusions from new studies and ensuing regulatory decisions in this report.

4.2.1 Orchard applications

Issues identified in interim report

Results (from available data and modeling) from the interim assessment indicated:

- Unacceptable MOE for M/L/A for high volume ground rig spraying of large areas (>20 ha/d). This finding was irrespective of the use of tractors with enclosed cabs, and/or wearing of extra layer of protective clothing, and/or use of closed mixing systems.

- Unacceptable MOE for M/L/A for low volume ground rig spraying (mist blower[8]) of small and large areas (study range ~5 to 20 ha/d), using tractors without cabs. These risks were reduced to acceptable levels for small areas only (~ 5 ha/d) by the wearing of extra layer of protective clothing, or use of tractors with enclosed cabs.

- Unacceptable MOE for M/L/A for hand-spraying (knapsack) of large areas. These risks were reduced to acceptable levels by the wearing of extra layer of protective clothing.

[8] Surrogate for airblast spraying

Conclusions from new studies

With regard to Mixer/Loader (M/L) and Application (A), endosulfan (using ground air assist application with and without the use of closed cabins, ground air-shear spray and ground boom oscillating spray), acceptable MOE were determined for workers handling up to 40 kg ai/day and a work rate of 30 ha/day, when exposures for individual tasks were considered separately. MOE were acceptable for applicators with and without the use of head / face protection. Thus although required for M/L (due to acute inhalation risks), respirators are not required during application of the diluted product.

MOE for combined exposures (M/L/A/C) were acceptable for air assist with cabin, air shear with cabin, and oscillating boomspray applications.

MOE for combined exposures (M/L/A/C) were acceptable for air assist applications without cabins, where head/face exposure was included in the determination (i.e. where workers were not wearing a respirator/hat).

Acceptable MOE were determined for cleaning down (C) operations following mixing/loading and spraying.

No hand spraying, aerial application or re-entry studies were carried out for orchard applications.

4.2.2 Nursery crop applications

Issues identified in interim report

Results (from available data and modeling) from the interim assessment indicated:

- Unacceptable MOE for hand spraying of ornamentals (based on an application rate of 0.1 kg/ha per day).
- Risk for workers using hand-held equipment for greenhouse treatment could not be identified due to lack of measured or predicted (modeled) exposure data.

Conclusions from new studies

Studies were carried out for mixing/loading, hand-held spraying and cleaning down associated with nursery crops. It was not clear from the studies whether high or low-pressure systems were used.

Acceptable MOE were determined for workers mixing/loading and cleaning down operations, where up to 0.5 kg endosulfan was handled per day.

Combined M/L/A and cleaning down exposure provided acceptable MOE for workers carrying out all activities.

No application or re-entry studies were carried out for greenhouses and no re-entry studies were carried out for outdoor nursery crops.

4.2.3 Broadacre applications

Issues identified in interim report

No measured exposure data were available in the interim report (APVMA 1998). Results (from modeling data) indicated:

- *Unacceptable* MOE for M/L/A for low volume boomspray (0.5 –2.1 L product in 100-400 L water) of areas (~50 ha/d) irrespective of the use of tractors with enclosed cabs.
- *Acceptable* MOE for Applicators for low volume (0.5 L product in 400 L water) boomspray of areas (~50 ha/d).

Conclusions from new studies (Broadacre crops / aerial application)

Studies were carried out for mixing/loading endosulfan for aerial application and exposure to support workers (markers etc) using vehicles (including ATVs) and cleaning down operations.

Mixer/loader exposures were determined for bulk, mini-bulk and small containers in open and closed systems for aerial application of broadacre crops. The total endosulfan handled/day was 1470 kg ai based on an application rate of 2.1 L/ha and work rate of 2000 ha/day.

Acceptable MOE were determined for mixer/loaders using open/remote or closed base systems for aerial application.

Acceptable MOE were determined for aerial applicators (pilots), and support workers in vehicles and ATVs

Acceptable MOE were determined for workers conducting cleaning down activities.

Conclusions based on PHED data (Broadacre crops / ground application)

PHED data for ground application (boom spray) were recalculated using 0.5% and 1.52% dermal absorption rates for mixing/loading and application. Acceptable MOE were determined for workers open mixing/loading endosulfan for treatment of broad acre crops by ground application, with and without the use of gloves.

Acceptable MOE were determined for workers using open cab for ground application of endosulfan to broadacre crops, with and without then use of gloves.

Acceptable MOE were determined for workers open pour mixing and ground boom open cab application (combined activity) to broadacre crops, with and without the use of gloves..

4.2.4 Re-entry exposure

Issues identified in interim report

The information available for assessment for the interim report did not contain data on worker exposure during re-entry.

Clarke and Churches (1992) investigated re-entry exposure to cotton chippers in NSW. The total potential skin exposure was 12.2 mg/hr seven hours after endosulfan spraying to a 30 cm high crop and 19.8 mg/hr twenty-four hours after endosulfan spraying to a 50 cm high crop (NRA 1998).

A re-entry period of 24 hours was identified as inadequate. Results from this study indicated that a re-entry period would need to consider crop height.

In the absence of data, an interim re-entry period of 2-3 days was proposed pending submission and assessment of further information.

Conclusions from new studies

Initially re-entry exposure data was submitted only for cotton crops following ground and aerial application. No measured exposure data were provided for workers re-entering treated areas on day 0 and day 1 as the study authors observed the 48 hour re-entry interval stipulated on the label. Margins of exposure for other crops identified on labels were extrapolated from the DFR data in a re-entry study on melons, peaches and grapes (Singer, 1995). Transfer Coefficients determined from measured DFR data, dosimetry data, and generic TC for low and medium exposure were used to calculate the MOE and determine re-entry intervals for cotton, and for other crops .

Acceptable MOEs were obtained on day 0 for workers re-entering cotton fields, orchards and broadacre crops for various re-entry activities.

There are no PPE requirements following the re-entry interval.

4.3 CONCLUSIONS FROM OH&S ASSESSMENT

The following conclusions were determined following the assessment of OHS studies provided after the release of the interim report. These conclusions are further considered in conjunction with residues conclusions in formulating the final regulatory outcome, in section 7.

4.3.1 Use patterns

Satisfactory data from measurement or modelling

Acceptable worker exposure levels can be achieved for the use of endosulfan in nursery, orchard and broadacre use patterns. Consequently, on the basis that the APVMA is satisfied that the continued use of endosulfan for these uses would not be an undue hazard to the safety of people exposed to it during its handling, it is concluded that the following use patterns will continue to be permitted:

- nursery use applications.
- orchard use; ground rig applications.
- broadacre use applications; aerial applications and ground rig applications.

No suitable data provided

Uses of endosulfan for turf and hides were deleted from labels following the interim report on the basis that no information was provided and these uses were not supported by the states. However, these uses remained on two product labels and have been deleted as an outcome of the review.

4.3.2 Re-entry periods

The following re-entry period is considered appropriate for all endosulfan products:

- **Re-entry: Do not allow re-entry into treated areas until the spray has dried**.

4.3.3 Safety directions

The following amended safety instructions are required:

> Very dangerous particularly the concentrate product. Undiluted product poisonous if absorbed by skin contact, inhaled or swallowed. Will damage eyes. Will irritate the nose and throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. If clothing

becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water.
When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing], elbow-length PVC gloves, and a full facepiece respirator. When using the prepared spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing].

After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator (and if rubber wash with detergent and warm water) and contaminated clothing

Precautionary statement: For aerial application, support workers/markers should be protected by enclosed cabs

4.3.4 Outcome

The occupational health and safety evaluation found that the APVMA could be satisfied that the continued use of products containing endosulfan 350 g/L in EC formulations in all situations as currently permitted (except for turf and hides) would not be an undue hazard to the safety of workers exposed to it during its handling. The evaluation has determined that instructions on product labels be varied by deleting the use on turf and hides. The occupational health and safety evaluation also recommended that labels be varied to include new safety directions, re-entry periods and PPE requirements.

The occupational health and safety evaluation concludes that provided that labels are varied as proposed then the APVMA could be satisfied that continued use and other dealings of products containing endosulfan would not be an undue hazard to the safety of people exposed to it during handling.

5. WATER QUALITY MONITORING

5.1 INTRODUCTION

The APVMA interim report of the endosulfan review (1998) concluded that, although well retained once in the soil, endosulfan contaminates the broader environment through spray drift, volatilisation and particle transport. This may occur aerially and, more importantly, by storm runoff leading to riverine contamination. The major metabolite, endosulfan sulphate, retains the toxicity of endosulfan and persists in soil and sediments.

Particular problems occurred with storm runoff into rivers, as endosulfan has high aquatic toxicity. For example, there have been a number of reported fish kills in NSW and Queensland between the mid 1970s and 1995. Whilst agricultural chemicals are not the only cause of fish kills, and despite difficulties in determining exact causes, cotton pesticides, in particular endosulfan, have been most often implicated as causing the majority of those fish kills (Bowmer *et al.* (1995); Napier *et al.* (1998)).

Pesticide monitoring in cotton growing areas of NSW during the cotton season consistently found endosulfan at concentrations above ANZECC guidelines (ANZECC and ARMCANZ 2000) in at least 50% of samples through the 1990s. Despite limited information, it was believed that a comparable situation existed in Queensland rivers.

Whilst there were indications at the time of the interim report that the situation may have been improving, contamination levels were unacceptably high. A number of measures were put in place by the APVMA to address these problems, including tighter controls and restrictions on use. The cotton industry introduced a Best Management Practice Manual, with guidelines to promote adoption of improved agricultural practices. Amongst other things, the aim of these measures was to minimise the impact of pesticides on riverine environments.

The APVMA interim report concluded that the cotton industry needed to demonstrate improved practices and reduced environmental contamination. The report required that:

> "*Trends in environmental contamination and total quantity used will be re-evaluated by 30 June 2001 to determine whether endosulfan use should be continued*".

As an interim outcome of the review, data was required to be submitted in relation to this requirement and, in addition, the report specified other requirements aimed at reducing environmental impacts from endosulfan use.

To measure the effectiveness of measures taken to protect the waterways in cotton regions, an evaluation has been conducted of river monitoring data provided by the then Department of Land and Water Conservation (Muschal (2000a); Muschal (2000b). This, together with other related information (Mawhinney, 2003) provides the basis of the following discussion.

5.2 DISCUSSION

Water quality is largely determined by land use, geology, climate, riparian vegetation and stream flow. Agricultural activities have a number of impacts on water quality including the levels of pesticides in waterways.

5.2.1 Water Monitoring in Rivers of NSW

The Central and North West Regions Water Quality Program (CNWRWQP) was jointly funded by the then Department of Land and Water Conservation and the water users of the Macintyre, Gwydir, Namoi and Macquarie Valleys. The project commenced in the early 1990s and focused on

the impacts of agriculture on water quality. Amongst other things, the levels of pesticides were monitored, at a number of sites, over a ten-year period.

Spray drift, vapour transport and runoff are the main pathways for pesticide transport into river systems. Spray drift and vapour both contribute low level but almost continuous inputs to the riverine ecosystem during the peak spraying season. The likelihood of pesticide drift is influenced by weather conditions, the method of application, equipment used and crop structure. Runoff tends to provide occasional high concentrations of pesticide contamination. Pesticides in runoff can be dissolved in the water, bound within sediments or adsorbed on to suspended particles.

The number and percentage of samples containing endosulfan contamination in the Namoi, Gwydir and Macintyre Valleys in each sampling year are given in Table 5.1. The number of samples includes all sampling sites across each valley, not just those located in the main cotton growing areas.

Table 5.1: No. & % endosulfan detections across the Namoi, Gwydir and Macintyre Valleys (1991/92 - 2001/02)

Year	No. Samples	Endosulfan
1991/92	296	174 (59%)
1992/93	299	194 (65%)
1993/94	210	137 (65%)
1994/95	281	135 (48%)
1995/96	291	169 (58%)
1996/97	395	207 (52%)
1997/98	404	196 (49%)
1998/99	400	182 (46%)
1999/00	413	126 (31%)
2000/01	438	76 (17%)
2001/02	290	14 (4.8%)

No results subsequent to 2001/02 available

The most commonly detected insecticide was endosulfan, with approximately 50% or more of samples containing residues of endosulfan during 1991-1999. The highest levels of contamination occurred in the periods 1991-94, coinciding with the rapid expansion of the cotton industry and a relatively low awareness of best practice methods compared to today's standards.

In 1998-1999 endosulfan residues were detected in cattle. This led to the introduction of greater restrictions on endosulfan use, and further emphasis on the cotton industries best management strategy. These two factors resulted in a dramatic reduction in endosulfan in the three valleys during 2000-2001 and 2001-2002.

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). This compares to previous years ranging from 32% (1991–92), peaking at 49% (1993–94), to 8% (2000–01). Endosulfan concentrations in the Gwydir River catchment in 2001–2002 were the lowest detected since 1991, although endosulfan and/or metabolites were detected at 9 out of 70 (13%) locations. This compares to previous detections ranging from 80% (1991–92) to 29% (2000–01). Furthermore, in recent years endosulfan concentrations fell below the ANZECC guidelines value for 99% ecosystem protection across all three valleys.

It was noted that this reduction may be due to a combination of factors including the implementation of best agricultural management practices, and a lack of runoff during 2001–02.

A report of the Mid-Lower Lachlan River Pesticide Study (NSW Department of Land & Water Conservation, June 2002) detected endosulfan in 35% of samples measured. However, it should be noted that the analytical procedures used were qualitative only, and not confirmed, and the majority of detections were at or slightly above the limit of detection. For this reason, whilst these results cannot be ignored, any conclusions to be drawn from this study are limited.

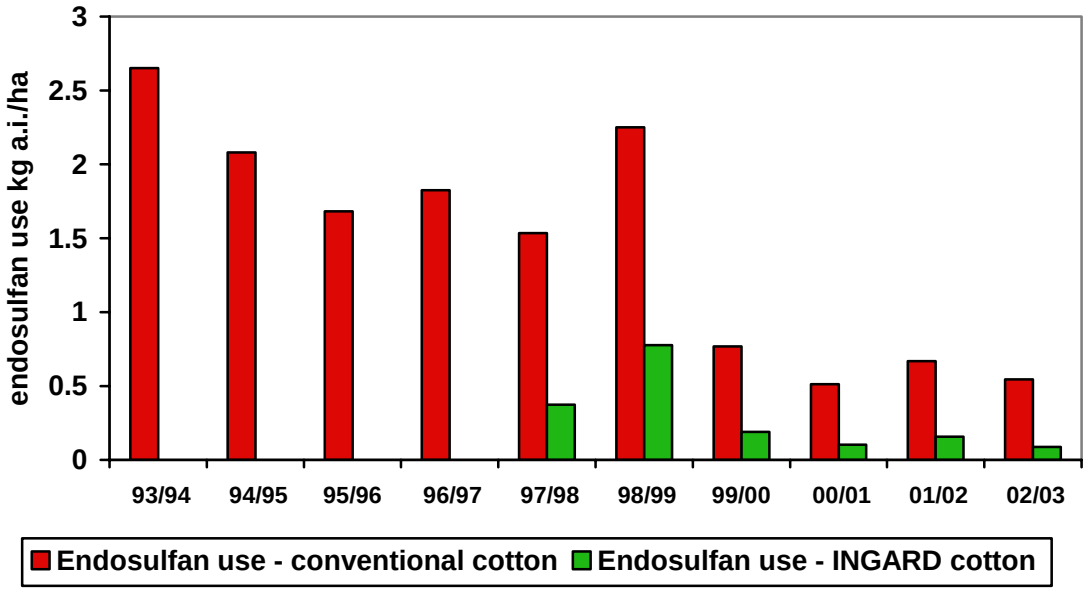
5.2.2 Endosulfan Usage

The figure below shows usage rates for endosulfan in Australia for the periods 1993-2003 (personal communication, B Pike, 2003. Data collected the annual Market Survey of Cotton Consultants Australia).

For the years up to 2000, use includes ultra-low volume (ULV) formulations plus emulsifiable concentrate (EC) formulations. Since 2000, only EC has been used. Usage has been converted to kg active ingredient /ha. For all years EC use has been generally consistent between 0.5 and 1 kg ai/ha.

INGARD (genetically modified cotton) was grown in 1996/97 but no specific data is available. It was noted that data for the limited area of Bollgard cotton in trials in 2001-02 indicated a reduction of only 30% endosulfan usage compared to INGARD. Endosulfan is a very good aphicide and it does not flair mites so it has a definite place in managing Bollgard as well.

Fig 5.1. Endosulfan usage rates in Australia



5.3 CONCLUSION

The monitoring results available to the APVMA adequately demonstrate 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.

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

5.4 WATER QUALITY REFERENCES

ANZECC and ARMCANZ (2000), *Australian and New Zealand guidelines for fresh and marine water quality*.

Bowmer K.H., Fairweather P.G., Napier G.N. and Scott A.C. (1995). *Review of data on the biological impact of cotton pesticides*. LWRRDC consultancy CWN12. CSIRO Division of Water Resources, Consultancy Report No. 95/13.

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Muschal M (2000b). *Central & North West Regions Water Quality Program. 1999-2000 Report on Pesticides Monitoring*. NSW Department of Land and Water conservation. CNR2000.067)

Napier G.M., Fairweather P.G. and Scott A.C. (1998). *Record of fish kills in inland waters of NSW and Queensland in relation to cotton pesticides*. WETLANDS (*Australia*), **17**: 60-71.

NSW Department of Land & Water Conservation (June 2002), *Draft Mid-Lower Lachlan River Pesticide Study 2001 – 2002*.

6. ENDOCRINE DISRUPTION

6.1 INTRODUCTION

The APVMA interim report on the review of endosulfan (1998) assessed a comprehensive toxicity data package. The major hazard associated with endosulfan was the high acute toxicity through exposure by ingestion, skin contact or inhalation. It was found that endosulfan does not persist for long periods in the tissues or organs of animals, and it was concluded that endosulfan was unlikely to bioaccumulate in humans.

There was no increase noted in the incidence of cancer arising from high concentrations and long exposure periods to endosulfan in the diet. It was also concluded that endosulfan was not likely to have any harmful effects on reproduction or cause birth defects. Endosulfan was not found to cause damage to genetic material and there was no evidence of disruption to the endocrine hormonal system.

In examining the issue of whether endosulfan is a xenoestrogen, the interim report concluded that toxicology studies did not indicate that endosulfan induces any functional aberrations that might result from disruption of endocrine homeostasis. However, a US EPA RED (Reregistration Eligibility Decision), finalised in 2002, identified endosulfan as "a potential endocrine disruptor".

Subsequent to the interim report, the APVMA decided to re-examine the issue of endocrine disruption for endosulfan. In doing so, the objective was to:

1) examine the US EPA RED report and attendant information regarding endosulfan, and identify and clarify variations from previous conclusions reported in the interim report;
2) specifically re-examine the issue of possible endocrine disruption caused by endosulfan.

In conducting this re-examination, the conclusions of the interim report relating to the chronic, developmental and reproductive studies have been reconsidered, together with the relevant findings of the US EPA RED report. Additionally all of the published literature relevant to the endocrine disrupting potential of endosulfan to the end of April 2003 has been evaluated.

6.2 DISCUSSION

Definition and mechanisms

Several definitions for *endocrine disruptor* have been proposed.

The OECD (1998) defines an endocrine disruptor as "an exogenous substance or mixture that alters function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub)populations. A potential endocrine disruptor is an exogenous substance or mixture that possesses properties that might be expected to lead to endocrine disruption in an intact organism, or it progeny or (sub)populations".

The working definition used in the final report of the US EPA Endocrine Disruptor Screening and Testing Advisory Committee (1998) for an endocrine disruptor is "an exogenous chemical or mixture that alters the structure or function(s) of the endocrine system and causes adverse effects at the level of the organism, its progeny, populations or subpopulations of organisms, based on scientific principles, data, weight-of-evidence, and the precautionary principle". The National Research Council of the USA has adopted the term *hormonally active agents*, in place of the term *endocrine disruptor chemicals* (1999).

Australian and US EPA policy relating to Endocrine Disruptor Effects

Australian agencies consider that endocrine disruption is not considered to be an adverse end-point *per se*, but rather is a mode or mechanism of action potentially leading to other toxicological or eco-toxicological outcomes, for example, reproductive, developmental, carcinogenic or ecological effects. These effects are routinely considered in reaching regulatory decisions (at least for pesticides, food additive chemicals and high production volume industrial chemicals for which the required toxicology database is extensive). This position is quite similar to the US EPA position.

The US EPA view of endocrine disruption has resulted from changes in its underlying legislation. The US EPA is required to develop a screening program to determine whether certain substances (including all pesticide active and other ingredients) "may have an effect in humans that is similar to an effect produced by a naturally occurring oestrogen, or other such endocrine effects as the Administrator may designate." Consequently, the US EPA has broadened its definition of endocrine disruption to include the androgen and thyroid hormone systems, in addition to the oestrogen hormone system, and also included the evaluation of potential effects in wildlife.

The Australian vs USA position on endosulfan as an endocrine disruptor

The APVMA interim report on endosulfan stated that:

- "Several recent studies have reported that endosulfan, alone or in combination with other pesticides, may have oestrogenic binding capability, and possibly potential for perturbation of the endocrine system. To date, the available studies show only very weak binding to hormone receptors *in vitro*, and the evidence for any relevance to adverse physiological effects *in vivo* is extremely limited"; and that
- "Long term bioassays, and reproductive and developmental toxicology studies in experimental animals, do not indicate that endosulfan induces any functional aberrations which might result from disruption of endocrine homeostasis."

The US EPA RED stated that:

- "Exposure to endosulfan has resulted in both reproductive and developmental effects in non-target animals. Endosulfan exposure resulted in impaired development in amphibians, reduced cortisol secretion in fish, impaired development of the genital tract in birds and reduced hormone levels and sperm production and produced testicular atrophy in mammals. Additionally, endosulfan has been demonstrated to bind to the human oestrogen receptor and exhibit significant estrogenic activity. Whether the toxicity endpoints are a result of endocrine disruption is not known. However, it is clear that organisms treated with endosulfan did exhibit some toxic effects that have historically been associated with endocrine disrupting chemicals, for example, developmental and reproductive."

Both reports suggested that more information was needed.

Hence the main difference between the Australian and US EPA is primarily definitional. The APVMA report suggested that endosulfan does not appear to be significantly endocrine disruptive in mammals whereas the US EPA RED proposes that the weight of evidence from all studies (including amphibians, fish and birds) supports the designation of endosulfan as a potential endocrine disruptor.

6.3 CONCLUSIONS

From this assessment, it was determined that the overall conclusions and regulatory recommendations of both regulators are very similar.

The APVMA and US EPA reviews of endosulfan evaluated comparable databases and adopted similar regulatory approaches on most issues. The specific issue of whether endosulfan should be categorised as an endocrine disruptor remains as one significant difference between the two agencies. However, this arises mainly from the US EPA inclusion of data from all endocrine systems as well as potential effects in wildlife. Both agencies state that further testing of endosulfan using validated assays would be valuable and might help to further characterise effects related to endocrine disruption.

The APVMA evaluation reported the 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 is adequately sensitive and protective against potential endocrine disruption by endosulfan.

The US EPA evaluation noted the effects seen in test animals and argued additionally that effects seen in amphibians, fish, birds and hormone receptor studies are indicative of potential endocrine disruption.

It is concluded from the APVMA re-examination of possible endocrine disruption caused by endosulfan that, from a public health perspective, there are no compelling reasons to change the conclusions of the APVMA interim report on 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. Furthermore, while endosulfan may be relatively persistent in the environment and is capable of long-range transfer, it does not appear to bioaccumulate. 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.

7. REVIEW OUTCOMES

In addition to the interim outcomes of the review announced in 1998,subsequent actions taken by the APVMA, and the evaluation of supplementary information, the regulatory actions discussed below have been determined.

7.1 Regulatory Actions

Following consideration of the available data, the following outcomes have been reached:

1) Revoke the suspension of endosulfan products.
2) Vary conditions of label approval.
3) Affirm product registrations.
4) Cancel product labels that do not contain adequate instructions.

Affirm active constituent approvals

At the time of the interim review outcomes, August 1998, the APVMA affirmed the approval of endosulfan active constituents.

Revocation of suspension

To implement the findings of the review of endosulfan (variation to labels and affirmation of registration), the APVMA revoked the suspension of endosulfan product registrations and label approvals listed in Appendix 1.

Vary conditions of label approval

The APVMA is satisfied that the conditions to which label approvals are currently subject can be varied in the way outlined in sections 7.2 through to 7.6, to ensure that the requirements for continued label approval will be complied with. Therefore the APVMA has varied the conditions of label approval for labels listed in the following table.

Product Number	Product Name [Registrant]	Label approval to be varied
32799	Nufarm Endosulfan 350 EC Insecticide [Nufarm Australia Ltd]	32799/0801
45570	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	45570/1099
45838	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0800
50004	Thiodan EC Insecticide [Bayer CropScience Pty Ltd]	50004/0702
52163	Farmoz Endosulfan 350 EC Insecticide [Farmoz Pty Ltd]	52163/0899

Affirm registrations

The APVMA is satisfied that provided product labels are varied as proposed that the products meet the prescribed requirements for continued registration and therefore affirms product registrations as listed in Appendix 1.

Cancellation of label approvals

The APVMA is not satisfied that the approved labels listed below contain adequate instructions and cancels these approvals.

Product Number	Product Name [Registrant]	Label approval numbers
32799	Nufarm Endosulfan 350 EC Insecticide [Nufarm Australia Ltd]	32799/0899 32799/0400 32799/1000 32799/0301
45570	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	455700/0299
45838	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899 45838/0300
50004	Thiodan EC Insecticide [Bayer CropScience Pty Ltd]	50004/0899 50004/1099

7.2 USE PATTERNS

The overall conclusions for the Review are summarised below.

Use Pattern (label)	Review Outcome	Reason for Outcome		
		No data	dietary exposure risk	trade risk
ORCHARDS: Citrus fruits, pome fruits, assorted tropical / subtropical fruits (inedible peel), tree nuts (excluding Banana)	Retain	-	-	-
Bananas	Delete	X	-	-
BROADACRE: Pasture, chou moeiller, vetch, lucerne, clover and medic crops	Delete	X	-	-
Pulse crops (*late season use*)	Delete	-	-	X
Pulse crops (*pre-emergent use only*)	Retain	-	-	-
Cereal crops (excluding sorgum and maize) (*late season use*)	Delete	-	-	X
Cereal crops (excluding sorgum and maize) (*pre-emergent use only*)	Retain	-	-	-
Sorghum and Maize	Delete	-	-	X
Oilseed crops (excluding cotton and	Delete	-	-	X

Use Pattern (label)	Review Outcome	Reason for Outcome		
		No data	dietary exposure risk	trade risk
peanuts) (*late season use*)				
Oilseed crops (excluding cotton and peanuts) (*pre-emergent use only*)	Retain	-	-	
Cotton	Retain (label restraint)	-	-	-
Peanuts	Delete	X	-	-
Legume vegetables	Delete	-	-	X
HORTICULTURE: Berries & other related fruit	Delete	X	-	-
Bulb vegetables	Delete	X	-	-
Leafy vegetables	Delete	-	X	-
Cole vegetables (except Broccoli, cabbage (head) and cauliflower)	Delete	-	X	-
Broccoli, cabbage (head) and cauliflower	Retain	-	-	-
Brussel sprouts	Delete	-	X	-
Fruiting vegetables, other than curcurbits (excluding sweet corn)	Retain	-	-	-
Cucurbits	Retain	-	-	-
Sweet corn	Delete	-	-	X
Root & tuber vegetables	Retain	-	-	-
Stalk and stem vegetables	Retain	-	-	-
Stone fruit	(*1)	-	-	-
OTHER: Native trees & shrubs, direct seeding	Retain	-	-	-
Nursery and ornamental crops	Retain	-	-	-
Tobacco	Retain	-	-	-
Hides	Delete (*2)	X	-	-
Lawn/turf	Delete (*2)	X	-	-

X potential risk from some use patterns
*(*1) Stone fruit currently not on label, but were assessed in the report. Apricots had dietary concerns.*
*(*2) As a result of review outcomes from the interim Endosulfan Report (August 1998). Worker exposure data/support for these use patterns was not provided for assessment.*

7.3 WITHHOLDING PERIODS

The following withholding period statements have been included on product labels, in relation to the above MRLs:

Crop	Withholding period
Citrus fruit	Do Not Harvest For 3 Days After Application
Pome fruit	Do Not Harvest For 28 Days After Application
Avocado, Kiwifruit, Mammey, Passionfruit, Pomegranate, Sapodilla	Do Not Harvest For 14 Days After Application
Custard Apple, Guava, Lychees, Longans, Mango, Pawpaw, Persimmon, Rambutan, Tamarillo	Do Not Harvest For 7 Days After Application
Broccoli, Cabbage, Cauliflower	Do Not Harvest For 7 Days After Application
Cucurbits	Do Not Harvest For 3 Days After Application
Capsicum, Tomatoes	Do Not Harvest For 3 Days After Application
Cape gooseberry, Eggplant, Okra	Do Not Harvest For 7 Days After Application
Beetroot, Carrot, Potato, Sweet Potato, Taro	Do Not Harvest For 14 Days After Application
Celery, Rhubarb	Do Not Harvest For 7 Days After Application
Cashews, Pecans, Pistachios	Do Not Harvest For 14 Days After Application
Macadamias	Do Not Harvest For 2 Days After Application

Crop	Harvest	Grazing
Pulse Crops (Adzuki beans, Chickpeas, Cow peas, Faba beans, Field peas, Lentils, Lupins, Mung beans, Navy beans, Pigeon peas)	Nil	Do Not Graze Or Cut For Stockfood For 7 Weeks After Application.
Cereals (Barley, Oats, Rye, Triticale, Wheat	Nil	Do Not Graze Or Cut For Stockfood For 10 Weeks After Application
Oilseeds: Canola (Rapeseed), Linseed, Soya beans, Safflower, Sunflowers)	Nil	Do Not Graze Or Cut For Stockfood For 8 Weeks After Application
Cotton	Do not harvest for 8 weeks after application	

7.4 RE-ENTRY PERIODS

The following re-entry period has been added to endosulfan product labels.

Re-entry: Do not allow re-entry into treated areas until the spray has dried.

7.5 LIVESTOCK FEEDING RESTRAINTS

The following livestock feeding restraints have been included on all product labels where appropriate:

- This product must not be used on cotton where cotton trash, fodder or stubble (excluding seed and hulls) will or may be fed to livestock.

- Do Not Feed Cotton Fodder, Stubble or Trash To Livestock
- Do Not Feed Vegetable Wastes or Wrapper Leaves of Treated Vegetable Crops to Livestock
- Do Not Feed Treated Melons or Melons Crops To Livestock
- Do Not Feed Treated Tomato Crops To Livestock

Livestock Destined for Export Markets

The label withholding periods for grazing only apply to stock slaughtered for the domestic market. Some export markets apply different standards. To meet these standards, ensure that the Export Slaughter Interval (ESI) is observed before stock are sold or slaughtered.

Export Slaughter Interval (ESI) – 21 days

Livestock that have been grazing on or fed treated crops (Except for label exclusions – cotton, melons, tomato, vegetable wastes/wrapper leaves) should be placed on clean feed for 21 days prior to export slaughter.

7.6 SAFETY DIRECTIONS

The following amended safety instructions have been included on labels:

> *Very dangerous particularly the concentrate product. Undiluted product poisonous if absorbed by skin contact, inhaled or swallowed. Will damage eyes. Will irritate the nose and throat and skin. Avoid contact with eyes and skin. Do not inhale vapour. If clothing becomes contaminated with product or wet with spray remove clothing immediately. If product on skin, immediately wash area with soap and water. If product in eyes, wash it out immediately with water.*
>
> *When opening the container and preparing spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing], elbow-length PVC gloves, and a full facepiece (or half facepiece and goggles) respirator.*
>
> *When using the prepared spray, wear cotton overalls buttoned to the neck and wrist [or equivalent clothing].*
>
> *After use and before eating, drinking or smoking, wash hands, arms and face thoroughly with soap and water. After each day's use, wash gloves, respirator (and if rubber wash with detergent and warm water), goggles and contaminated clothing*

Precautionary statement: For aerial application, support workers/markers should be protected by enclosed cabs.

7.7 Maximum Residue Levels

The following amendments to the MRL Standard have been made.

Changes to Table 1 of the MRL Standard for Endosulfan

Code	Food	MRL (mg/kg)	
		Delete	Add
FI 0026	Assorted tropical and sub-tropical fruits – edible peel	T2	–
FT 0030	Assorted tropical and sub-tropical fruits – inedible peel	T2	2
FB 0018	Berries and other small fruits	T2	–
VB 0400	Broccoli	T2	1
VB 0041	Cabbages, head	T2	1
VB 0404	Cauliflower	T2	1
GC 0080	Cereal grains	T0.2	0.1
FC 0001	Citrus fruits	T2	0.3
OC 0691	Cotton seed oil, crude	T0.5	–
MO 0105	Edible offal (mammalian)	T0.2	0.2
PE 0112	Eggs	T*0.05	0.02
VC 0045	Fruiting vegetables, cucurbits	T2	1
VO 0050	Fruiting vegetables, other than cucurbits	T2	1
VP 0060	Legume vegetables	T2	-
ML 0106	Milks [in the fat]	T0.5	–
ML 0106	Milks	–	0.02
MM0095	Meat (mammalian) [in the fat]	0.2	0.2
SO 0088	Oilseed	T1	1
VA 0385	Onion, bulb	T0.2	–
FP 0009	Pome fruits	T2	1
PO 0111	Poultry, edible offal of	0.2	*0.01
PM 0110	Poultry meat [in the fat]	0.2	0.05
VD 0070	Pulses	T1	*0.1
GC 0649	Rice	T0.1	–
VR 0075	Root and tuber vegetables	T2	0.5
VA 0388	Shallots	T2	–
VS 0078	Stalk and stem vegetables	T2	1
FS 0012	Stone fruits	T2	–
DT 1114	Tea, Green, Black	T30	–
TN 0085	Tree nuts	T2	0.05

Changes to Table 4 of the MRL Standard for Endosulfan

Code	Animal Feed Commodity	MRL (mg/kg)	
		Delete	Add
-	Primary Feed Commodities	0.3	–
AB 0226	Apple pomace, dry	–	1
-	Cereal forage (green)	–	0.3
-	Citrus pulp and pomace, dry	–	2
-	Forage of pulse crops (green)	–	0.3
-	Forage of oilseed crops	–	0.3
AS 0081	Straw and fodder (dry) of cereal grains	–	0.4
-	Straw and fodder (dry) of oilseeds	–	*0.1
-	Straw and fodder of pulse crops	-	0.3

APPENDIX 1: Active constituent approvals and product registrations

ACTIVE APPROVALS

Approval Number	Active Name	Approval holder
44012*	ENDOSULFAN	EXCEL INDUSTRIES (AUSTRALIA) PTY LTD
44093	ENDOSULFAN	MAKHTESHIM-AGAN (AUSTRALIA) PTY LIMITED
44288	ENDOSULFAN	FARMOZ PTY LTD
44305	ENDOSULFAN	BAYER CROPSCIENCE PTY LTD
57040#	ENDOSULFAN	BECOT PTY LTD T/AS IMTRADE COMMODITIES

Approval granted after the commencement of the review, that is subject to the outcomes of the review

* Active constituent approval cancelled 1999.

PRODUCT REGISTRATIONS AND LABEL APPROVALS

Product Number	Product Name [Registrant]	Label approval numbers
32799	Nufarm Endosulfan 350 EC Insecticide [Nufarm Australia Ltd]	32799/0899 32799/0400 32799/1000 32799/0301 32799/0801
45570	Thionex 350 EC Insecticide Spray [Makhteshim-Agan (Australia) Pty Ltd]	455700/0299 45570/1099
45838	Endosan Emulsifiable Concentrate Insecticide [Crop Care Australasia Pty Ltd]	45838/0899 45838/0300 45838/0800
50004#	Thiodan EC Insecticide [Bayer CropScience Pty Ltd]	50004/0899 50004/1099 50004/0702
52163#	Farmoz Endosulfan 350 EC Insecticide [Farmoz Pty Ltd]	52163/0899

Registration granted after the commencement of the review, that is subject to the outcomes of the review

APPENDIX 2: Public comments on the Endosulfan draft report (May 2004)

The endosulfan draft review report was released for public comment in May 2004. Its availability was announced on the APVMA website, APVMA gazette and direct mail to review participants. Eighty Five submissions were received with a number of issues identified.. These are discussed below.

Listed below are respondents views on the issue (***bold, italics***) and the APVMA's response to the comments (normal text). All responses received have been taken into consideration in revising the draft report to produce this report.

Dermal absorption factor

Dermal absorption values of 0.5% (concentrate) and 1.52% (dilutions) should be adopted for calculation of dermal absorbed dose in the OH&S assessment.

Following the assessment of the supplementary data, a dermal absorption factor of 0.5% for concentrates i.e. mixing/loading, and 1.52% for spraying and re-entry activities was used in the OHS risk assessment.

The dermal absorption value used in re-entry calculations should be the value relating to absorption of concentrate product, not diluted product.

Given the comparatively short time interval between treatment and re-entry, an endosulfan deposition rate of 3.0 $\mu g/cm^2/h$ is likely to be approaching the maximum rate at which exposure would occur. If endosulfan accumulated on the skin at a constant rate throughout an 8-hour workday, a peak dermal concentration of 24 μg endosulfan/cm^2 would be attained. This is similar to the mid concentration used in the *in vivo* dermal absorption study of Craine (1988) (at which endosulfan penetration attained 46%) and to the lowest concentration used in the *in vitro* absorption study of Davies (2002). Therefore, the extent of dermal absorption arising from re-entry exposure would be closely similar to that which has been estimated for endosulfan in diluted spray mixture (i.e. 1.52%), rather than the extent of absorption from exposure to concentrated formulations. A dermal absorption factor of 1.52% will be used for re-entry exposure assessment.

Re-entry periods

Earlier re-entry is permitted once spray is dry on the treated crop, provided cotton overalls buttoned to the neck and wrist and impermeable gloves are worn. Re-entry to cotton fields is acceptable at day 0, based on calculations of re-entry exposure using average study derived transfer co-efficients.

Following assessment of the supplementary data (re-entry and dermal absorption) the re-entry interval proposed in the draft report has been amended to permit re-entry on day 0 after the spray had dried (refer to the Technical Report*).*

The following statement should be added to the re-entry interval section of the endosulfan label: No re-entry restrictions apply for bare earth applications.

The OHS re-entry risk assessment is conducted based on use pattern information provided on the label. Application to bare earth could not be assessed, however, considering that the risk for

workers entering treated areas is acceptable on day 0 the risk is expected to be acceptable in the pre-emergent stage, where no foliage exists.

Re-entry exposure calculations in non-cotton crops should use DFR values from specific endosulfan studies in peaches and melons, which are submitted for evaluation.

DFR values from the re-entry study on melons, peaches and grapes were extrapolated to determine re-entry intervals for non-cotton crops.

Re-entry exposure in vegetables (excluding cauliflower) should be calculated using a generic TC of 2500.

Re-entry exposure in vegetables was calculated from DFR data and a generic transfer coefficient of 2500 for vegetables (high exposure).

Re-entry period of 72 hours and 5day (pecans)be amended to 24 hours.

The re-entry period has been amended to day 0 following assessment of data provided.

Exposure from open cab vs closed cab

One submission suggests differentiating between open and closed cabins for broadacre uses as is the case for the orchard and horticulture uses, or changing orchard and horticulture uses to match broadacre requirements i.e. respirator at all times.

Based on supplementary data, the risk for workers using open cabins is acceptable. However, based on the hazard classification, workers should wear a respirator if the concentration of endosulfan in the spray is>1%.

Endosulfan use in cotton

The general public, growers and one community group made submissions in support of the continued use of endosulfan in cotton. Argument was provided including:

- ***Endosulfan is IPM friendly and has only a moderate impact on beneficial insects***
- ***Cost effective***
- ***Controls heliothis along with a wide range of sucking pests***
- ***Does not flare secondary pests , therefore reducing further insecticide use***
- ***The recent track record of the Australian Cotton industry shows that residue violations in meat can be avoided***
- ***Endosulfan contamination in major water catchments has dramatically been reduced over the last 10 years***

Cotton use pattern remains with appropriate feeding restraints and improvements in industry practices, i.e. MoU between Cotton Industry, Cotton Ginners and Cattle Council of Australia.

Endosulfan use in legume vegetables

Various grower groups provided submissions supporting the continued use of endosulfan on legume vegetables, sweet corn, with appropriate ESI information on labels. One submission made the following comments The APVMA should have regard for NVD and CVD awareness

as part of any risk assessment. Concerns that horticultural industries do not use CVDs and development of adequate management practices are required.

The APVMA will delete use patterns for legume vegetables and sweet corn due to lack of adequate management processes (CVDs) within horticultural industries. The APVMA is not able to recommend a feeding restraint for crops or crop by-products that are typically used as livestock feeds. Any ESI proposal would be unmanageable as indicated in interim regulatory action.

Early stage foliar application

One submission requested the APVMA to consider other early stage foliar applications for pest control that may still meet residue recommendations.

Consideration has been given to all foliar application of endosulfan and the review has determined late stage applications to oilseeds including soya beans will be deleted from labels. There was not enough data provided to re-consider other early season uses. If interested parties were to generate appropriate data for this type of assessment then it could be considered as part of the registration process.

Dietary intake concerns

Registrants, government agencies and individuals supported the deletion uses that cause dietary concerns including the use patterns for grapes and other berry fruit; bananas; bulb vegetables; Brussels sprouts and other unspecified brassica vegetables; leafy vegetables; peanuts; clover, lucerne, medics, pastures. One submission requested the APVMA to reconsider the decision for the deletion of the use pattern in brussel sprouts

The APVMA review of endosulfan will delete all use patterns for which no residues data were provided, or dietary concerns were identified. The review will delete the use pattern for Brussels sprouts due dietary concerns and large variation in data and few trials. If grower groups or registrants hold appropriate data to support these deleted uses, consideration could be given through the registration process.

Livestock feeding

Submissions were received supporting deletion of use patterns identified as being high risk for livestock feeding, as well as support for feeding restraints.

The APVMA will delete all use patterns for which livestock feeding issues were identified as restraints are not easily manageable. feeding restraint for vegetables wastes and wrapper leaves will be retained.

The APVMA is not able to recommend a feeding restraint for crops or crop by-products that are typically used as livestock feeds. It is impractical to recommend a clean feed interval for opportunistic feeding situations where there are no data.

Withholding periods/maximum residue limits

Several grower organisation requested that some withholding periods be reconsidered, with a view to shortening the proposed WHP where the data provided for the review supported this for tropical fruits – inedible peel; mango, avocado, passionfruit, pawpaw, rambutan, and cucurbits

Recommend WHP of 7 days for mango, pawpaw, rambutan, custard apple, persimmon. WHP for passionfruit remains at 14 days, due to extrapolation from other crops.
Recommend WHP of 3 days for all cucurbits, as there are no dietary concerns and appropriate data were submitted

There was a request to extend WHP for cotton to match spray dates stated in Conditions of Use On Cotton.

WHP for cotton is 8 weeks after application to match spray dates published in APVMA Gazette (January 2005).
Cotton use pattern remains with appropriate feeding restraints and improvements in industry practices, i.e. MoU between Cotton Industry, Cotton Ginners and Cattle Council of Australia.

The APVMA was asked to consider whether it is appropriate establish MRLs for livestock feeds that exceed the MFL.

The proposed MRL's for livestock feeds were reconsidered and the following determinations have been made. Grazing WHPs for forage of cereal grains have been extended from 8 weeks to 10 weeks and for pulses from 6 weeks to 7 weeks; Oilseeds will remain at 8 weeks. MRLs for forage of cereals have been amended from 0.5 mg/kg to 0.3 mg/kg; the MRL for pulse forage has been amended from 0.5 mg/kg to 0.3 mg/kg.

Labelling

Several submission received argued that feeding restraint statements that were proposed in the draft final review report are not enforceable, due to user of the feed being 3rd party to the user on the crop. Extension advice may help to alleviate situations where opportunistic feeding occurs. Use of cotton trash as a livestock feed will continue in drought situations. The APVMA should provide advice to manage such situations. Requests to develop EI information on labels to meet export market MRL was also received.

The feeding restraint statements have been revised and the APVMA maintains that feeding of some crop waste is not considered to be good agricultural practice. Export Slaughter Intervals (ESI) have been included on labels manage trade and also feeding situations if they occur for all crops excepting cotton, melons, tomatoes and vegetables.. An ESI of 21 days clean feed has been included on the label to cover trade situations and meet Codex MRL.
The Cotton use pattern remains with appropriate feeding restraints and improvements in industry practices, i.e. MoU between Cotton Industry, Cotton Ginners and Cattle Council of Australia.

The APVMA has been requested to provide draft labels at time of public consultation to clarify changes to existing labels.

This request has been noted and where possible will be accommodated. The review of endosulfan has resulted in many changes and additions to the product labels and use requirements over a long period of time. All previous changes to labels as an outcome of the interim decision in 1998 will remain in force and are currently on the label. All of the proposed amendments resulting from current evaluations were clearly specified in the report.

Concerns were raised about spray concentrations and rates that are lower than current label rates and have been assessed for citrus use pattern, in absence of efficacy review.

The Lower rate assessed and lower MRL proposed for citrus fruits was at the request of industry. The Efficacy consideration was undertaken in parallel with the review following data submission prior to 2003. The efficacy of this use pattern was reviewed through the state system with a consolidated reviewers report being made available to the APVMA. The Efficacy review concluded that "The data submitted support the label claim for lower rates on spined citrus bug".

Inclusion of a label statement should be considered to account for stubbles that may be treated for mite control.

The regulatory outcome of this review has resulted in deletion of the late stage heliothis use patterns for cereals, pulses and oilseeds and restriction to bare earth treatments only. The necessity for an additional label statement is unclear and registrant should generate residues data to support their concerns.

Lack of information on spray drift in the draft final report. APVMA to consider that ground-based application will also have associated drift concerns.

Trade risks from contamination of pasture or other stock feed caused by spray drift from nearby endosulfan applications have been considered at several stages of the endosulfan review and substantial regulatory measures have been taken to control those risks. The rigorous requirements imposed on endosulfan applications to cotton and the subsequent withdrawal of all ULV formulations of endosulfan have led to greatly reduced risk from spray drift. An increased awareness of risk factors by both endosulfan users and stock producers has also contributed significantly to that lowered risk.

Regulatory actions taken in 2002 have further reduced risks from applications to crops other than cotton by removing a significant number of uses from labels. This report describes additional reduction of crop uses permitted on endosulfan labels. With all late season non-cotton broad-acre uses gone and early season uses quite limited, the situation is vastly changed from what it was only a few years ago and overall spray drift risk from non-cotton applications is very much lower. Concerns raised over bare-earth and early post-emergent spraying for mites are addressed by the large droplet placement requirement and controls for other risk factors on the new endosulfan label.

The APVMA is currently completing and refining a comprehensive review of its approach to spray drift risk assessment and risk management. The outcomes of this review are expected to begin being implemented by the beginning of 2006. As a part of that implementation, all products for which there are potential spray drift concerns will be reviewed in relation to that specific risk and their labels will be updated to match the new spray drift management standards.

Endosulfan products with new approved labels as required by this review's outcomes present a level of spray drift risk control higher than perhaps any other group of products. Current understanding of spray drift risk by endosulfan user and cattle producer industries as well as incorporation of established Commodity Vendor Declarations is high. It is expected that spray drift risk will be adequately managed during the 2005-2006 cropping season.

When the new spray drift risk assessment and risk management guidelines presently under development are adopted, the endosulfan labels will be reassessed and altered where needed to conform to the new standards. This approach is preferable to delaying the completion of the entire endosulfan review with all of its other regulatory features until early 2006 in order to accommodate the completion of the new spray drift management guidelines.

The APVMA was requested to consider residues data submitted in support of a registration submission.

This new data which was submitted as part of a registration submission has been considered where appropriate.

Import tolerances

APVMA/AQIS should seek import tolerances for Australia's major meat markets

Import tolerances are outside the scope of the APVMA review. The necessity for import tolerances for endosulfan is questioned as there are MRLs/tolerances for meat in Australia's major meat export destinations. Refer to section 2.20 of the residues report.

Retention of uses

A request was received to have use on seed destined exclusively for sowing purposes be retained.

The APVMA advises that use of endosulfan for commercial seed production may be considered through the minor use permit system. Applicants would need to provide evidence that this use is only minor and that appropriate quality controls are in place to eliminate any potential for treated seed, waste and stubble to be feed to livestock.

All other comments if not addressed in this appendix have been addressed in the amended Technical Report.

Attachment 1: MOU

Memorandum of Understanding
Between Australian Cotton Industry and Australian Beef Cattle Industry

This agreement addresses the issue of certain by products of cotton , in particular, cotton gin trash, failed cotton crop and cotton crop residue and the potential for these by products which may have been treated with the pesticide endosulfan, to be fed to livestock and cause residue violations in meat.

It is entered into to ensure that both industries, those being the Australian Cotton Industry and the Australian Cattle Industry each take appropriate actions within their respective industries to ensure that the cotton by products referred to above are not consumed by livestock .

The overall objective of this agreement is to ensure that appropriate and effective safeguards are put in place by both parties to protect against violative residues in meat, and so protect Australia's meat trade.

Towards this objective, the following principles are agreed

to: **The Australian Cotton Industry agrees to the**

following:

1. Cotton ginners will adhere to the principles set out in The Australian Cotton Ginners Association Code of Practice which relate, to The Management of Cotton Gin Trash and Management of Cotton Gin Motes. The appropriate extract from this code of practice is attached as **Appendix 1** to this document.

2. Individual cotton growers will ensure that livestock do not have access to cotton fields and/or irrigation infrastructure during the growing season where they could access plant material contaminated with endosulfan or other pesticides. Cotton growers will take all due care to ensure such access is precluded and should therefore ensure that;

    a. All fences are maintained to an appropriate standard which prevent stock access
    b. Access by gate or ramps or other entry points for stock or machinery is monitored and restricted
    c. where appropriate, signage is placed on property boundaries and at gates to ensure stock managers are aware of crop treatment.

3. Individual cotton growers will ensure that livestock are not allowed access to fields containing cotton crop residue at the conclusion of the season until cotton crop residue has been ploughed in and an appropriate time has elapsed to allow for the depletion of pesticide residue. Cotton growers will take all due care to ensure such access is precluded.

4. Cotton growers will ensure that Cotton crops which have failed prior to maturity, not to be cut and baled for the purposes of feeding to livestock as fodder and will take all due care to ensure stock access to failed crop material is precluded.

5. Cotton Australia Ltd will reinforce to cotton growers, the legislative requirements set out on registered endosulfan pesticide labels, which relate to the feeding of cotton gin trash, cotton crop residue and failed cotton crop material to livestock.

6. Cotton Australia will insert the principles outlined in points 2,3 an 4 into the appropriate section of the industry Best Management Practices Manual.

7. Cotton Australia will reinforce to cotton growers the legislative requirements set out for use of registered endosulfan pesticide labels which relate to the management of spray drift and communication of spray events to relevant stakeholders

8. Cotton Australia and the Cotton Ginner's Association recognizes the SAFEMEAT^{TM} Commodity Vendor Declaration and By Product Vendor declaration as the primary and most effective means of communicating chemical residue risks in stockfeeds. Cotton Australia and the Cotton Ginner's Association will work with SAFEMEAT^{TM} to expand awareness of the Commodity Vendor Declarations (CVD) And By-Product Vendor Declarations (BPVD) in the Cotton Industry, communicate to CA and ACGA members SAFEMEAT^{TM} updates on the CVD and BPVD, and agree to encourage use of these management tools.

The Australian Beef Cattle Industry Agrees to the following:

1. Cattle Council of Australia and the Australian Lot Feeders Association will actively support the position taken by the cotton industry not to allow supply of cotton by-product (including cotton gin trash, failed crop residue, and cotton crop residue) to any person for the purposes of feeding the material to livestock – including drought situations.

2. Cattle Council of Australia and the Australian Lot Feeders Association reinforce through State Member Organisations, Affiliate Member Organisations and Meat and Livestock Australia will reinforce to Cattle producers and the wider the livestock industries the risks associated with feeding of cotton by product to livestock.

3. Cattle Council of Australia and the Australian Lot Feeders Association will through SAFEMEAT continue to support the use of the National Vendor Declaration and accompanying NVDs and CVDs as an effective method of identifying livestock which are at risk of residue violations.

4. Cattle Council of Australia and the Australian Lot Feeders Association will support the continuation of National Residue Survey monitoring for endosulfan residue in meat of livestock and the work of the "Endosulfan Task Force" through the Beef Industry Advisory Committee (BIAC) and SAFEMEAT Committees

5. Cattle Council of Australia and the Australian Lot Feeders Association will assist in the investigation of 'reported actions of either industry's members in not complying with the principles set out in this agreement.

6. Cattle Council of Australia and the Australian Lot Feeders Association will work to insert appropriate information on the risks associated with cotton crop by products into the guidelines and information which support the Cattlecare, NFAS and LPA programs.

General

1. In the event of either a cotton industry member or livestock industry member becoming aware of an incident or action involving cotton by product which could place livestock at risk of obtaining endosulfan residue, the matter should be reported to the State Residue Co-ordinator in the appropriate state.

2. Where it becomes necessary for the State Residue Co-ordinator to make further enquiries with respect to a reported incident, initial contact should be made with either Cotton Australia Ltd or Cattle Council of Australia, who agree to notify the other party in a timely manner.

3. It is the responsibility of the State Residue Co-ordinator to advise Safemeat of the situation if it is considered necessary.

Definitions

For the purposes of interpreting this document the following definitions should be noted.

(a) Endosulfan - Any registered pesticide product which has as its active ingredient endosulfan or product which contains endosulfan as one of its ingredients.
(b) Cotton By-Product - Materials which are a by-product of the production of cotton plants which include cotton gin trash, cotton crop residue and failed cotton crop material.
(c) Cotton Gin Trash – Bark, cotton stalk fragments, leaves and other material such as dirt, which are separated from cotton lint during the ginning process.
(d) Cotton Crop Residue - Cotton stalks, desiccated leaves which remain in field after the cotton lint is harvested.
(e) Failed Cotton Crop Residue - whole cotton plant which has not reached maturity but has been abandoned .

Term and Termination

Cotton Australia, Cattle Council of Australia, Australian Lot Feeders Association and the Australian Cotton Ginners Association agree that this memorandum shall remain in effect until terminated by either party upon 90 days notice to the other party, where it is authorized to do so under its governing legislation. All parties agree that where one group determines that such termination is justified by inadequacy of the existing regulatory mechanisms, or the effectiveness of the MoU in managing risk, that all groups support the immediate review of products containing the active Endosulfan which are used in the cotton industry.

Cotton Australia Ltd

Date: 16/6/05

Cattle CourKii of Australia

Date: 16/6/05

Australian Cotton Ginners Association

Date: 14/

Australian Lot,N eed-6rs Association

Date: 9/6/05

Appendix 1:

Australian Cotton Ginners' Association ATTACHMENT 1

DRAFT CODE OF PRACTICE

Management of Cotton Gin Trash

Waste cotton gin by- product commonly referred to as *cotton gin trash* has the potential to contain residues of certain [2]*pesticides* which are applied to an actively growing cotton crop during the cotton growing season. If consumed by livestock, the [3]*residues* contained in the trash may accumulate in the meat and/or fat of animals and give rise to unacceptable pesticide residues which may place meat export markets at risk.

All reasonable efforts must be taken to ensure that livestock including beef cattle, dairy cattle, sheep and goats are not fed cotton gin trash or allowed access to this material.

Cotton Ginners will implement the following practices aimed at preventing livestock from gaining access to cotton gin trash and potential pesticide residues.

(1) Cotton Ginners take all reasonable steps to ensure that cotton gin trash remains under their direct control and supervision until such times as it can be disposed of by approved means.

(2) The *approved* method of disposal at this point in time will be by composting. The following two methods of composting may be employed:

a. Natural Composting — A process where cotton gin trash is placed in 1-1.5 metre high rows and allowed to decompose over time with the assistance of natural rainfall and bacterial action.

b. Mechanical Composting - A process where cotton gin trash is placed in 1 — 1.5 metre high rows and allowed to decompose over time with mechanical interventions including maintaining moisture content at optimal levels with the addition of water and the mechanical turning of windrows.

(3) Composting sites will minimize the generation of dust by the appropriate application of water.

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[i] Waste material including dirt, bark, leaves, bracts, and other vegetative matter removed from cotton lint during the cotton ginning process.

2 Pesticides are synthetic chemical substances as defined by various state legislation, which may be applied to cotton crops to control insects, weeds, fungi or control cotton plant growth.

' Residue refers to the small concentrations of pesticides which may remain on plant material & in soil after application. Pesticides break down at varying rates according to the pesticide's characteristics and may be present after long periods of time in the case of persistent pesticides.

(4) Composting sites will be located in areas where rainfall runoff can be controlled so as to prevent contaminated water moving to neighbouring properties, or entering water courses or areas where livestock may consume the water.

(5) Composting sites should be located such that they are not in flood-prone areas.

(6) In the first instance, cotton gin trash will be composted, if possible, on the property where the ginning facility is located. If available land area is, or becomes a constraint, composting may be conducted on an alternative land area under the control of the ginning organisation or on an area of land owned by another person acting under contract to the ginning organisation. Where composting takes place remotely from the gin site or under contract, the composting site must comply with (3) (4) and (5) above.

(7) Where it is necessary for gin trash to be removed from the gin site to another location for the purposes of composting, gin operators will take all reasonable steps to ensure that:

a. the land area on which composting will be conducted is securely fenced and secured so as to prevent livestock accessing the cotton gin trash /compost .
b. during the transporting process, cotton gin trash is prevented from falling from the transport vehicle(s).
c. appropriate security including the locking of access gates and regular surveillance of the site is implemented so as to prevent the unauthorized entry and removal of trash by unauthorized persons.
d. each section of fence and access gates securing the cotton gin trash /compost bears a prominent sign stating:

"COTTON GIN TRASH / COMPOST
DO NOT FEED TO LIVESTOCK"

e. if the cotton ginner or any person responsible for the security of the cotton gin trash/compost has reason to believe that the compost enclosure has been accessed by unauthorized persons, livestock have accessed the cotton gin trash/compost or material has been removed from the enclosure, then full details must be reported immediately to the *State Residue Co-ordinator* in the appropriate state.

(8) In the case of a cotton gin operator engaging a landholder in a contract to compost cotton gin trash on his property, the cotton gin operator will include all of the requirements set out in item (7) above in the formal contract. In addition the cotton gin operator will include any additional terms and conditions he deems necessary to ensure the security of the cotton gin trash /compost in the particular circumstances. The cotton gin operator or his representative will further advise the contractor of the risks to livestock posed by cotton gin trash and the importance of security of the cotton gin trash/compost. A representative of the cotton ginning organisation will inspect the contract site on at least a weekly basis to ensure compliance of contract terms and conditions.

(9) In the case of both cotton gin site and contract composting operations, the cotton ginning organisation will maintain accurate records of composting activities. Records will contain dates and quantities of cotton gin trash placed in composting sites; dates and quantities and details of compost transported, and details of any incidents of unauthorized access or removal of cotton gin trash/ compost.

(10) Compost from each season will be maintained separately, and remain identifiable so that age of compost can be readily determined.

(11) Cotton ginners will not supply any person with cotton gin trash for any purpose including garden mulch, direct feeding to livestock or as an ingredient for manufactured stock feed.

(12) Where the cotton ginning 'operation is part of a large integrated farm which also operates a livestock enterprise on that farm, the gin operator will ensure that livestock do not have access to the ginning facilities or associated module yards, seed storages, cotton gin trash storages, gin yard water runoff storage dams or cotton gin trash composting areas. In addition, the operator will not use cotton gin trash as a stock feed including as an emergency drought fodder.

(13) Other than for the purposes of composting cotton gin trash as a contractor to a cotton gin operator, individual growers who seek to obtain gin trash generated from the ginning of cotton grown on their own property, will not be supplied with cotton gin trash by the cotton gin operator.

(14) Where cotton gin trash has been composted and has degenerated to a material of a soil like nature, it may be used as a soil enhancement material.

(15) Where state legislation is in force which classifies cotton gin trash as a particular class of waste, cotton gin operators will comply with that legislation in the handling of the material for the purposes of disposal. In complying with that legislation, all reasonable effort will be taken to ensure that any risk of access to the cotton gin trash by livestock is eliminated.

(16) In the event of cotton gin trash being spilled from a transport vehicle during transport, the gin operator must, upon being made aware of the spill, take immediate action to retrieve the spilled material and remove it to the composting site.

Management of Cotton Gin Motes

Cotton gin motes should not be fed to livestock and as such, from the cotton gin operators position, will be treated the same as cotton gin trash where they are to be disposed of rather than be used for low grade industrial cotton products. Disposal will be by composting in accordance with the code of practice requirements for cotton gin trash.