

REPORT - 15-

ON

CHLORPYRIPHOS

SUBMITTED BY

THE EXPERT COMMITTEE

CONSTITUTED TO REVIEW THE USE OF

CHLORPYRIPHOS IN THE COUNTRY

TO

PLANT PROTECTION ADVISER

TO THE GOVERNMENT OF INDIA

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PREAMBLE

Chlorpyrifos is an organophosphorus pesticide. It is registered under the Insecticides Act, 1968 for use in agriculture and for termite control in buildings. Recently, US Government has phased out some of the uses of Chlorpyrifos. Therefore, on the directives of Deptt. of Agriculture and Cooperation, a Committee has been constituted by the Plant Protection Adviser to the Government of India to review the various uses of Chlorpyrifos in the country.

Three meetings of the Committee were held. The information was collected on various aspects of Chlorpyrifos including chemistry, registration status; production/consumption and use status of Chlorpyrifos in India and globally, on-going practices by the Pest Control Operators for home (post construction termiticide) uses of Chlorpyrifos; its toxicity, the reason for the ban/restriction in other countries and its relevance under Indian scenario and the alternatives available globally and in India under the Insecticides Act. The views of State Directors of Agriculture and State Agricultural Universities were also obtained. After considering the available national and international information, the views of the various Agricultural Universities and the State Department of Agriculture, Pesticide Industry Associations and the valuable input from members, the Committee finalise its recommendations.

2.

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BACKGROUND OF CONSTITUTION OF COMMITTEE

Government of India, Ministry of Agriculture (Deptt. of Agriculture & Cooperation) keeps on reviewing those pesticides which are banned or severely restricted in other countries of the World. Recently, US Government has banned most of the home uses of Chlorpyrifos in an ongoing effort to implement the Food Quality Protection Act, 1996 which requires a systematic review of all pesticides to ensure that they need tighter standards with a goal of protecting children foremost. In view of this, Deptt. of Agriculture & Cooperation has requested Plant Protection Adviser to the Government of India to take necessary steps to constitute Committee to review the use of Chlorpyrifos in the country (copy of letter of DAC at Annexure - I). Accordingly, a Committee has been constituted by the Plant Protection Adviser to the Government of India. The detail composition of the Committee and its terms of reference are at Annexure - II. Further due to non-availability of Dr. (Mrs) S.B. Lall, the Chairperson of the Committee after the first meeting i.e. 20.10.2000, it has been decided to nominate Dr. Ranjit Roy Chaudhury, President, Delhi Society for Promotion of Rational Uses of Drugs as the Chairman of the Committee in place of Dr. (Mrs.) S.B. Lall (Annexure - III) and also as per the communication received from Deptt. of Agriculture and Cooperation (copy at Annexure - IV), a representative of Pesticides Manufacturers and Formulators Association of India has been included in the Committee as a member. Accordingly, the revised composition of the Committee is at Annexure - V.

3. DETAILS OF THE MEETINGS HELD

1 The Committee held three meetings to discuss the various aspects of Chlorpyrifos use in the country.

The first meeting of the Committee was held on 20.10.2000 under the Chairpersonship of Dr. (Mrs.) S.B. Lall. In that meeting, the Committee decided to collect information on the identified parameters and to submit this information to Member-Secretary for compilation and discussion in the Second meeting of the Committee. The agenda and minutes of the first meeting are at Annexure VI (A) and VI (B) respectively.

The second meeting of the Committee was held on 8.1.2000 under the Chairmanship of Dr. R.R. Chaudhary, wherein the information collected by members of the Committee on various aspects of Chlorpyrifos was discussed. Based on the discussion, it was decided that the existing use of Chlorpyrifos as approved by the Registration Committee may be continued for controlling insect-pests in agriculture. It was also decided that antitermite use of Chlorpyrifos in buildings may be continued. However, the Committee was of the opinion that studies on inhabitant of different age groups regarding the impact of Chlorpyrifos treatment as termiticide for post construction use are required to be undertaken under Indian conditions within a period of one year. Further, the decision with regard to home use of Chlorpyrifos was deferred for the next meeting. The decision regarding some of the other issues viz. limit of Sulfotep impurity in Chlorpyrifos technical; and restricting/limiting the concentration on Chlorpyrifos solution to 0.5% for use as termiticide was also deferred for the next meeting. The agenda and minutes of the second meeting of the Committee are at Annexure VII (A) & (B) respectively.

The third and final meeting of the Committee was held on 28.2.2001 under the Chairmanship of Dr. R.R. Chaudhary. In this meeting, the Committee reiterated its earlier decision that the existing use of Chlorpyrifos as approved by the Registration Committee may be continued for controlling insects-pest in agriculture and Good Agricultural Practices are required to be observed specially during its use on fruits and vegetables so that the residues do not exceed the maximum limit allowed. The Committee also reiterated the need for specific studies regarding the impact of Chlorpyrifos treatments on inhabitants of different age groups when used as termiticide in buildings. The Committee also decided that the present status of 0.3% maximum of Sulfotep impurity in Chlorpyrifos technical may be allowed to continue. Regarding limiting/restricting, the concentration of Chlorpyrifos solution to 0.5% as termiticide, the Committee recommended that further studies regarding efficacy of 0.5% solution as termiticide in buildings are required to be carried out at CSIR Institute and till then use of 1% solution of Chlorpyrifos may be continued for antitermite treatment of buildings.

The Committee also decided that ready-to-use formulation of Chlorpyrifos of concentration ≤ 50 gm/lit may be considered for use in the household on case to case basis after evaluating the data submitted by the applicant regarding their safety. However, the use of concentrated formulations containing > 50 gm/lit Chlorpyrifos should be permitted through approved Pest Control Operators only provided the end use concentration do exceed 50 gm/lit. The Committee also recommended the incorporation of condition with reference to health monitoring studies on inhabitants on 100 houses within a period of one year in case of formulations belonging to Category II & III of household formulations (i.e. liquid formulations and formulations which emit vapour or gas by heating).

The detailed agenda and minutes of the 3rd meeting are at Annexure VIII (A) & (B) respectively.

4. CONCLUSION

1. Chlorpyrifos is approved for use on barley, paddy, gram, moong, sugarcane, cotton, groundnut, brinjal, mustard, cabbage, cauliflower, apple, ber, citrus, fruits. It is not approved for use on tomato in the country. The residues of Chlorpyrifos are not causing immediate danger to the environment in general and food commodities in particular.
2. Chlorpyrifos is approved for use as termiticide in building and forestry. No specific adverse effects have been reported during antitermite use of Chlorpyrifos in buildings. However, there are no specific studies regarding the impact of Chlorpyrifos treatment for termite control for post construction use on inhabitant of different age groups.
3. Only toxic impurity present in the Chlorpyrifos is Sulfotep which is allowed upto maximum of 0.3% in Chlorpyrifos technical registered in the country. No scientific data to reveal that 0.3% level is more toxic than 0.2% or vice-versa are available.
4. Presently 1% solution of Chlorpyrifos is recommended for use in antitermite treatment of buildings. The studies regarding efficacy of Chlorpyrifos 0.5% solution for termite control in buildings are available only for three years for three locations. As per the guidelines of the Registration Committee for approving the chemical for termite control in building, efficacy data generated at different locations for duration of five years is required. Therefore, data for two more years at three locations should be generated by the manufacturer of Chlorpyrifos at CSIR Institute. Till then use of 1% solution of Chlorpyrifos may continue for antitermite treatment of buildings.
5. Presently no formulation of Chlorpyrifos is registered for use in household in the country and therefore, no information on toxicity on adverse effect on Chlorpyrifos during its use in household is available in our country.
6. The Chlorpyrifos formulations of > 50 gm/lit concentration may require personal protective equipments during their use.

No. 17-D/2000-PP.I
Government of India
Ministry of Agriculture
Department of Agriculture & Cooperation

Krishi Bhawan, New Delhi
Dated: 16.11.2000

To

The Plant Protection Adviser,
Directorate of Plant Protection,
Quarantine and Storage,
NH-IV, Faridabad.

Subject: Review of the use of Chlorpyrifos in the country.

Sir,

I am directed to refer to your letter No. 20-31/2000-CIR dated 23.10.2000 on the subject mentioned, and to request that a representative of PMFAI may also be included in the committee constituted for the purpose.

Yours faithfully,



(G. Subramani)
Under Secretary to the Govt. of India

REVISED

EXPERT COMMITTEE TO REVIEW THE USE OF
CHLORPYRIFOS IN THE COUNTRY

Annexure - 1
14
- 28 -

- 1A. Dr. Ranjit Roy Chaudhury Chairman
President
Delhi Society for Promotion for
Rotational Uses of Drugs,
National Institute of Immunology
New Delhi.
2. Dr. Saroj Member
Addl. Director,
Ministry of Environment & Forest
CGO Complex, Lodhi Road,
New Delhi
3. Dr. O.P. Dubey, .. Member
ADG (PP), ICAR,
Krishi Bhavan,
New Delhi.
4. Dr. Brajendra Singh,
Entomologist (I).
Dte. of PPQ&S, Faridabad
5. Dr. Usha Gupta, .. Member
Prof. Deptt. of Pharmacology,
Maulana Azad Medical College,
New Delhi.
6. Dr. S.R. Gupta, stav, Member
Asstt. Director-General (PFA)
Ministry of Health & Family Welfare
Nirman Bhawan, New Delhi
7. Dr. V. Singh Member
Scientist - In Charge
B.P.H. Laboratory,
Central Building Research Institute
Roorkee - 247667
8. Director
Haltkin Institute,
Parel, Mumbai
9. Representative from .. Member
Pesticides Association of India
Mumbai
10. Representative from .. Member
Indian Crop Protection Association
Mumbai
11. Representative from .. Member
Indian Pest Control Association
Mumbai
12. Representative from PMFAI .. Member
Pesticides Manufacturers and
Formulators Association of India
Mumbai
13. Joint Director (Medical Toxicology), .. Member-
Dte. of PPO&S. Secretary

तार का पता: प्रोटेक्शन

Telegram: PROTECTION

टेलीफोन/Telephone:

पत्र सं./No. 20-31/2000-CIR

भारत सरकार

GOVERNMENT OF INDIA

कृषि मंत्रालय

MINISTRY OF AGRICULTURE

(कृषि एवं सहकारिता विभाग)

(DEPARTMENT OF AGRICULTURE AND CO-OPERATION)

वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय,

DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE

एन.एच.4, फरीदाबाद (हरियाणा)-121001

N.H.IV, FARIDABAD (HARYANA)-121001

दिनांक/Dated 3.10.2000

To

As per list enclosed.

Subject:- First meeting to review the use of Chlorpyrifos in the country.

Sir,

In continuation of this Directorate's letters of even numbers dated 19.9.2000 and 27.9.2000, it is to inform that the first meeting of the Expert Committee will be held on 20.10.2000 at 11.00 A.M. in the Conference Hall of Central Insecticides Laboratory, Faridabad. The agenda for the meeting is enclosed herewith.

You are requested to kindly make it convenient to attend the meeting.

Yours faithfully,

S. Kulshrestha

(S. Kulshrestha)
Joint Director (Med.) &
Member-Secretary

Agenda for the First meeting of the Expert Committee to review the use of Chlorpyrifos in the country.

Agenda
Item No.1

Background for constitution of the Committee

Chlorpyrifos is an organo-phosphorus pesticide registered under the Insecticides Act, 1968 for basic manufacture, import and use etc. Recently, the US Government has banned most of the home uses of Chlorpyrifos due to neurological health risks including blurred vision, muscle weakness, headache and memory loss. The ban is a part of an ongoing effort to implement the Food Quality Protection Act of 1996 which requires a systematic Government review to all pesticides to ensure that they meet tighter standards with the goal of protecting children foremost. The scientific review showed health risk to children who are more likely to come into contact with pesticides at home and schools and by eating food like grapes and apples. The ban has been announced by the US Government only on 8th June, 2000. The reports appeared in different newspapers in this regard may be seen at Annexure-I A & B.

While submitting the comments on these news reports, Plant Protection Adviser to the Government of India has suggested to Department of Agriculture & Cooperation for considering constitution of an Expert Committee to review the use of Chlorpyrifos in our country as the same has not so far been reviewed by any Expert Committee constituted by the DAC or by the Registration Committee constituted under the Insecticides Act, 1968. DAC has agreed to the suggestion of PPA and has requested him to take necessary steps to constitute the Committee and sent its report/ recommendations together with the comments of the Registration Committee thereon within two months (Copy of letter of DAC at Annexure-II). This matter was also discussed in 202nd meeting of the Registration Committee held on 17th August, 2000 wherein the Committee decided that the applications for registration of Chlorpyrifos be kept in abeyance till the response is received from the Deptt. of Agriculture and Cooperation regarding constitution of a Committee as proposed in the note of PPA to DAC and a representative from the Ministry of Environment & Forest may be included in the proposed Expert Committee by the PPA. Accordingly, after incorporating suggestions of the Registration Committee, an Expert Committee has been constituted by PPA. The composition of the Committee and its terms of reference may be seen at Annexure-III.

Agenda Discussion of modus operandi to be adopted to
Item No.2 review the use of Chlorpyrifos

Members may kindly see that as per the terms of reference of the Committee, use of Chlorpyrifos is to be reviewed for its continued use or otherwise in the country and in case the suggestion of ban or restriction on any specific issues, the alternatives/substitutes are required to be prescribed and/or type of restriction to be imposed is required to be identified. Critical aspects of the ban by the US vis-a-vis the situation in our country would be evident from the note of the PPA (copy of the relevant extracts is at Annexure-IV.). Therefore, the Committee may like to have information on the following parameters of Chlorpyrifos for the required review :-

1. Chemistry
2. Global registration status
3. Registration status in India
4. Global production/consumption of Chlorpyrifos
5. Production/consumption of chlorpyrifos in India
6. Uses of Chlorpyrifos
7. Uses of Chlorpyrifos in India as approved under the Insecticides Act, 1968.
8. Ongoing practices by the Pest Control Operators for home usage of Chlorpyrifos
9. Toxicity of Chlorpyrifos
 - (a) Acute toxicity
 - (b) Long-term and other toxicity
 - (c) Environmental toxicity
 - (d) Toxicity aspects for safe re-entry period.
10. Countries where Chlorpyrifos is banned/severely restricted.
11. Reason for their ban/restriction and their relevance to Indian scenario.
12. Alternatives available globally.

Members may like to deliberate to give opinion if information on any other parameter is required to fulfill the mandate assigned to the Committee.

Agenda Search for information/data on Chlorpyrifos
Item No.3

Effort made to collect the required information on Chlorpyrifos would be presented during the meeting by the Member-Secretary. Members are requested to make search for additional information/data which is relevant for the assigned purpose. This additional information may be sent to Dr.(Mrs.) S.Kulshrestha so that the same could be compiled for deliberations in the next meeting of the Committee.

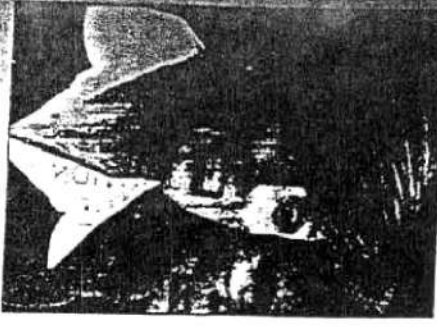
Agenda Any other item with the permission of the Chair
Item No. 4

The Nation

EPA bans pesticide as harmful to kids

Chlorpyrifos found in many common household products

By Alison Gerber
USA TODAY



By Doug Miller, AP
Browner: Pesticide could cause neurological damage.

WASHINGTON — The Environmental Protection Agency banned the most widely used pesticide in U.S. households Thursday, saying it could be harmful to children.

Chlorpyrifos, sold as Dursban or Lorsban, is found in more than 800 products, including flea collars and insecticides that kill cockroaches, termites, ants

and grubs. It's also sprayed in crops such as citrus and wheat.

The pesticide could cause neurological damage, EPA Administrator Carol Browner said. Dow AgroSciences and five other manufacturers of the chemical signed an agreement with the EPA that:

- ▶ Stops production of chlorpyrifos by December for over-the-counter sprays used in homes.
- ▶ Eliminates its use by the end of the year for exterminators spraying where children could be exposed, such as schools, day-care centers, parks and hospitals.
- ▶ Eliminates or cuts the amount of chlorpyrifos that can

be sprayed on crops such as tomatoes, apples and grapes by the start of the next growing season for each crop.

Critics of chlorpyrifos urged people to return unopened products and to stop using the pesticide immediately.

"The EPA showed great leadership in the face of oppressive lobbying," said Todd Hattenbach, a pesticide policy analyst at the Environmental Working Group. "But we're calling on retail chains like Wal-Mart and Home Depot to take these products off their shelves immediately."

Defenders of chlorpyrifos said the EPA used unreasonably high scientific standards to as-

sess the product's safety.

"With this new law, the rules have changed, and we felt we had no choice but to come to an agreement with the EPA," said Elin Miller, vice president of Dow AgroSciences. "But consumers can still feel very comfortable using this product. The safety remains the same."

Norman Goldenberg, vice president for technical services at Termitix, a national exterminating company, doubts the ban will affect the industry.

"There are plenty of alternatives," he said. "I don't think this is a crisis."

Termitix hasn't used Dursban since last last year, Goldenberg said.

पत्र सं./No. 20-31/2000-CIR

भारत सरकार
GOVERNMENT OF INDIA
कृषि मंत्रालय
MINISTRY OF AGRICULTURE
(कृषि एवं सहकारिता विभाग)
(DEPARTMENT OF AGRICULTURE AND CO-OPERATION)
वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय,
DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE
एन.एच.4, फरीदाबाद (हरियाणा)-121001
N.H.IV, FARIDABAD (HARYANA)-121001

दिनांक/Dated 3.10.2000

To

As per list enclosed.

Subject:- First meeting to review the use of Chlorpyrifos in the country.

Sir,

In continuation of this Directorate's letters of even numbers dated 19.9.2000 and 27.9.2000, it is to inform that the first meeting of the Expert Committee will be held on 20.10.2000 at 11.00 A.M. in the Conference Hall of Central Insecticides Laboratory, Faridabad. The agenda for the meeting is enclosed herewith.

You are requested to kindly make it convenient to attend the meeting.

Yours faithfully,

S.Kulshrestha

(S.Kulshrestha)
Joint Director (Med.) &
Member-Secretary

-33-

761 (P)
14/6

1. पत्र का नाम	Name of Paper	<i>The Hindu</i>	हिन्दुस्तान टाइम्स	Hindustan Times
2. प्रकाशन स्थान	Published at		नई दिल्ली	New Delhi
3. तारीख	Dated	10/6		

1805/JS (PP) / 2000
16/6

Dy. No. 1673 / AS (N)
Date: 14.6.2000

US Govt bans use of pesticide Dursban

Reuters
WASHINGTON, June 9

THE federal government on Thursday banned most home uses of the pesticide Dursban — the most widely used pesticide in the nation found in some 20 million homes — due to neurological health risks including blurred vision and memory loss.

The ban is part of an ongoing effort to implement the Food Quality Protection Act of 1996, which requires a systematic government review of all pesticides to ensure they meet tighter standards with the goal of protecting children foremost.

The EPA Administrator, Ms. Carol Browner, said the action followed a scientific review which showed health risks to children, who are more likely to come into

contact with the pesticides at homes and schools, and by eating foods like grapes and apples.

"In terms of how best to go about protecting our children, this was the fastest possible way for us to get the kind of (swift) reduction in the manufacturing of Dursban, Ms. Browner told reporters. "We are getting a 10-million-pound reduction in the manufacturing of this pesticide by the end of this year." EPA said blurred vision, muscle weakness, headaches and memory loss have been linked to exposure to large amounts of Dursban, leading to the restrictions announced on Thursday.

Ms. Browner said new, safer alternatives can replace Dursban.

Dursban is the popular trade name for a pesticide which has been used for three decades in households across the country.

Insecticide caution
Automatic insecticide dispensers used to control flying insects in restaurants, schools and hospitals could pose a public health risk if improperly installed, US officials said on Thursday.

The Atlanta-based Centre for Disease Control and Prevention (CDC), in what it said was the first report to document pesticide-related illnesses from aerosol dispensers, said the devices had made 97 people sick since 1986.

CDC researchers said people became ill from the pyrethrin or resmethrin pesticides used in the dispensers, which typically spray a fine mist of insecticide every 15 minutes around the clock.

Ailments generally involved eye, nose or throat irritation and, at times, respiratory, gastrointestinal, or neurological systems.

No.17-19/2000 PP.I
Government of India
Ministry of Agriculture
Department of Agriculture & Cooperation

Krishi Bhawan, New Delhi
Dated the 17th August, 2000

The Plant Protection Adviser,
Directorate of Plant Protection,
Quarantine and Storage,
NH IV, Faridabad.

Subject: Press Report on "US Govt. bans use of pesticide Dursban" -
facts regarding

Sir,

I am directed to refer to your Note No. 20-31/2000-CIR on the subject mentioned above and say that your proposal for constitution of an Expert Committee to review the use of Chlorpyrifos in the country has been approved. You are requested to please take necessary steps to constitute the Committee and to send its report / recommendations together with the comments of the Registration Committee thereon within two months to this Department.

Yours faithfully,



(G. Subramani)

Under Secretary to the Govt. of India

Sec (CIB/R.C)

For urgent action pl.

NR
24/8

J.D (mev)
Bnt ES

ETDANA
24/8/2000

750/PPA/2K
24/8/2000

1. Dr. (Mrs.) S.B.Lall, .. Chairperson
Addl. Professor,
All India Institute of Medical Sciences
New Delhi.
2. Dr. O.P.Dubey, .. Member
ADG(PP), ICAR,
Krishi Bhavan,
New Delhi.
3. Director, .. Member
Haffkin Institute,
Parel, Mumbai
4. Dr.Usha Gupta, .. Member
Prof. Deptt. of Pharmacology,
Maulana Azad Medical College,
New Delhi.
5. Dr. Y.Singh, .. Member
Scientist,
Central Building Research Institute,
Roorkee, U.P.
6. Dr. S.R. Gupta, .. Member
Asstt. Director-General (PFA),
Ministry of Health & Family Welfare,
Nirman Bhavan, New Delhi.
7. Representative from Ministry of .. Member
Environment & Forest
8. Representative from ICPA .. Member
9. Representative from BAI .. Member
10. Representative from IFCA .. Member
11. Entomologist (Insecticides), .. Member
Dte. of PPQ&S.
12. Joint Director (Medical Toxicology), .. Member*
Dte. of PPQ&S. Secretary

Terms of Reference

1. To examine the toxicity, persistence and safety during various uses of Chlorpyrifos under Indian conditions and to make appropriate recommendations for its continued manufacture, import and various types of uses in the country or otherwise.
2. To suggest the suitable substitutes in case any of uses of Chlorpyrifos is considered for ban in India.
3. To suggest the extent of restrictions required to be imposed on any use of Chlorpyrifos in India if it cannot be banned altogether.

PPA may also like to approve the following for the functioning etc. of the Committee:

1. The Committee may evolve its own procedure and methodology for functioning and obtaining for any relevant data from any Department of Central/State Governments/private organisations/persons etc.
2. TA/DA to the members of the Committee will be met by the Organisations from where their pay is being drawn at present.

ANNEXURE-IV

RELEVANT EXTRACTS FROM THE NOTE OF PLANT PROTECTION
ADVISER TO THE GOVERNMENT OF INDIA

Chlorpyrifos is registered under the Insecticides Act, 1968 for basic manufacture, import and use, etc. The total quantum of indigenous production of Chlorpyrifos in the country could be perused as under:-

(M.T. (Tech. Grade))

Year	Production
1994-95	758
1995-96	1106
1996-97	1590
1997-98	3581
1998-99	5694 (6.4% total of pesticides production)

(Source: Department of Chemical and Fertilizers. Information for 1999-2000 is yet to be consolidated by the said Department)

A total number of 21 companies have been granted registration under the Insecticides Act, 1968 for indigenous production of Chlorpyrifos. However, only 8 are expected to be actually producing this pesticide at present as under:-

It is also relevant to mention that as per telephonic information received from the Pesticides Association of India, M/s.Gharda Chemicals have exported 600 MT of Chlorpyrifos during 1999-2000. In monetary terms, the export was of the order of US \$ 3.5 million. About 65% of the quantum of export was to USA and the remaining to Far East, European and South American countries.

2. The salient feature of the press report (Annexure-I A & B) are as under:-

- i) US Government has banned most of the uses of Chlorpyrifos due to neurological health risks including blurred vision, muscle weakness, headaches and memory loss. The ban is a part of ongoing effort to implement the Food Quality Protection Act of 1996 which requires a systematic Government review of all pesticides to ensure

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they meet tighter standards with the goal of protecting children foremost. The scientific review showed health risk to children, who are more likely to come into contact with the pesticides at homes and schools and by eating food like grapes and apples.

- ii) The Environmental Protection Agency (EPA) in the USA is a Regulatory Body for registration of pesticides. The Administrator of EPA has indicated that by taking the swift action to protect children, there would be considerable reduction in the manufacturing of Chlorpyrifos. Such a reduction would be of the order of 10 million pounds by the end of 2000. It has also been expressed that safer alternatives would replace the Chlorpyrifos.
- iii) Automatic insecticide dispensers used to control flying insects in restaurants, schools and hospitals etc . pose public health risk. One of the Centres for Disease Control and Prevention based at Atlanta has reported pesticide-related illnesses from aerosol dispensers. The names of pesticides used in these dispensers are pyrethrin or resmethrin. **In our Country none of the synthetic pyrethroids registered for household use are approved for use through automatic insecticide dispensers involving a time bound automatic spray mechanism (in comparison to the USA).**

3. The US Government has announced aforesaid kind of ban on use of Chlorpyrifos only on 8th June, 2000. Therefore, Chlorpyrifos has not so far been reviewed by any Expert Committee constituted by the DAC or by the Registration Committee constituted under the Insecticides Act, 1968.

4. Chlorpyrifos was originally registered in favour of now known as M/s.De-Nocil company. Therefore, they were asked to provide the facts from their Principals in the USA. The information submitted by them is at Appendix-I. This information reveals that US EPA and registrants of Chlorpyrifos have agreed to the following modifications:-

- b) Indoor areas where children will not be exposed, including only ship holds, railroads, boxcars, industrial plants, manufacturing plants, or food processing plants.
- c) Outdoor areas where children will not be exposed.
- d) Non-structural wood treatments including fence posts, utility poles, railroad ties, landscape timbers, logs, pallets, wooden containers, poles, posts, and processed wood products.
- e) Public health uses for professionals only.

5. Current status of chlorpyrifos registration/use and the points for consideration:-

- i) The use of Chlorpyrifos is allowed in our country on apples and grapes for which US EPA mandates to significantly lower the residues beginning from next growing season. Use of Chlorpyrifos on tomato is not approved under the Insecticides Act, 1968. Under the Prevention of Food Adulteration act, 1954, a tolerance limit of 0.5 mg/kg (ppm) has been fixed for fruits. **Considering the limitations for monitoring residues of pesticides in our country, it is suggested that the use of Chlorpyrifos should be totally banned for grapes and apples.**
- ii) Chlorpyrifos is registered for termite control in pre- and post- construction in buildings in our country. US EPA recommended the product for restricted use and also recommended to limit use to 0.5% solution. Further, the post-construction use of whole house or spot and local use will be phased out beginning from end of this year to 2001-2002. The pre-construction use will be phased out from 2004-2005. So far approved alternative to Chlorpyrifos for termite control in building is only lindane. The earlier known termiticides like Aldrin, Chlordane and Heptachlor have already been banned in our country.

i) Agricultural/Food uses:

- a) The uses on tomato will be cancelled and tolerance will be revoked. The post-bloom application on apple will be prohibited (only pre-bloom, dormant application is allowed) and tolerances in apples and grapes will be lowered. The action of revoking/lowering tolerances will be taken by the beginning of next growing season while use prohibition will be implemented w.e.f. August-September, 2000. This action will eliminate dietary risk concerns for children and others.
- b) All agricultural uses of Chlorpyrifos will be given revised restricted entry intervals by the end of this year. It will help mitigate worker's risks for agricultural uses.

ii) Home uses

Home lawn and most other outdoor uses, crack and crevice and most other indoor uses will be phased out from this year and the retailers will stop sale by 31.12.2001. The post construction whole house, spot and local post construction use as termiticide will also be phased out from this year to the end of 2001 while for pre-construction termiticides the production will stop w.e.f. 31.12.2004 and use will be stopped w.e.f. 31.12.2005.

iii) Non-residential uses:

Its uses in indoor and outdoor areas such as schools, parks where children could be exposed will be cancelled beginning from this year and the retailers will stop sale by 31.12.2001.

iv) Restricted non-agricultural uses:

Certain non-agricultural uses of Chlorpyrifos with certain restrictions have been allowed as -

- a) Residential use of containerized baits.

Considering the serious health hazards of Chlorpyrifos and also the need of termiticides a critical review would now be necessary. Pest control operators are using Chlorpyrifos for various kinds of anti-termite treatments. Therefore, the Indian Pest Control Association needs to be consulted in the matter. **Keeping in view these facts, a review for imposing restrictions on use of Chlorpyrifos for termite control should be given priority.**

- iii) No formulation of Chlorpyrifos is registered till date for use in household. However, an application of Chlorpyrifos 2% ready-to-use paint for use on wood furniture is pending in the Registration Secretariat.
- iv) USA follows the concept of "Restricted Entry Intervals" ranging from 1-10 days to ensure safety to the workers for re-entry in the pesticide treated crops. This concept is not being regulated in our country. **Considering the risk of Chlorpyrifos exposure to the agricultural workers, it is suggested that this aspect should be reviewed by the Agricultural Scientists and Medical Experts for taking a definite view about safety intervals in terms of re-entry period.**

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Dr. (Mrs.) S. Kulbreshtha
Joint Director (Medical toxicologist)
Directorate of Plant Protection,
Quarantine & Storage
Ministry of Agriculture
Department of Agriculture and co-operation
N.H.-IV, Faridabad -121 001

Dear Madam,

Sub: Chlorpyrifos - Risk Assessment by United States
Environmental Protection Agency (US EPA)

At the outset, I wish to thank you for your time and patient hearing to our views in response to your query with regard to the risk assessment as announced by United States Environmental Protection Agency (US EPA) for Chlorpyrifos.

As already explained to you, the risk assessment by USEPA was necessitated due to introduction of Food Quality Protection Act, 1996 (FQPA) which established new and more stringent standard for the regulation of pesticides in the United States. USEPA is required to complete the assessment process of all the organophosphate insecticide by the year 2006. Chlorpyrifos is the first of the reevaluated product under the new safety standards of FQPA.

As a result of this reevaluation, some of the uses are restricted or eliminated, the details of which are presented in Annexure I.

As you will note from the above restriction imposed in crop segment, we do not have label claim for tomato and the use on Apple (for aphid control) and grapes (for root grub control as soil drench) are limited. Other than this, there is no restriction on any other crop use.

Amongst the non-crop use, in Indian context, the use of chlorpyrifos is limited only to pre and post construction of buildings. USEPA has allowed the product for pre construction use till December, 2005. However, based on the results of an exposure study specific to this application, this date may be further extended.

Further, our principals have entered in an agreement with USEPA on the dead line of the mitigation measures, the summary of which is attached as Annexure II.

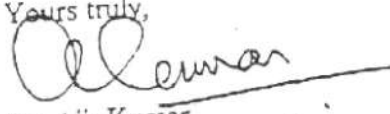
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It will not be out of place to mention that at the time USEPA was making the risk assessment, almost the same time FAO/WHO JMPR conducted the review evaluation for chlorpyrifos and confirmed the product safety. We shall, in due course of time forward the relevant documents in support of this claim. In the meantime, we request you to kindly refer to Annexure III, wherein you will note that safety standards set by other regulatory authorities are up to 300 times greater than that recently established EPA.

Should you like to have any specific information on the subject, we shall be most glad to furnish the same.

Thanking you and assuring you of our best cooperation,

Yours truly,



Dr. Ajit Kumar
Sr. Manager - Registration &
Regulatory Affairs

CC: Plant Protection Advisor to Government of India,
D PPQ & S, Faridabad

Dr. Brijendra Singh (Ento I)
D PPQ & S, Faridabad

Summary of Chlorpyrifos Agreement with U.S. EPA

February 1, 2001	<p>No distribution or sale of End Use Products by a Registrant for:</p> <ul style="list-style-type: none"> • Pre-construction termite control (unless max. 0.5 % a.i.); • Post-construction termite (except spot and local at 0.5 % a.i.); • Indoor residential (except baits); • Indoor non-residential (except baits and use in warehouses, ship holds, railroad box cars, industrial plants, manufacturing plants or food processing plants); • Outdoor residential use (except fire ants mound drench and mosquito control); • Outdoor non-residential use (except golf course turf, road medians and industrial plant site turf at max. 1 lb./a.i. per acre; mosquito control; fire ants mound treatment; non-structural wood treatment); • Agricultural uses without new Restricted Re-entry Intervals (REIs).
December 31, 2001	<p>No retail sales of Use for:</p> <ul style="list-style-type: none"> • Pre-construction termite control (unless max. 0.5 % a.i.); • Post-construction termite (except spot and local at 0.5 % a.i.); • Indoor residential (except baits); • Indoor non-residential (except baits and use in warehouses, ship holds, railroad box cars, industrial plants, manufacturing plants or food processing plants); • Outdoor residential use (except fire ants mound drench and mosquito control); • Outdoor non-residential use (except golf course turf, road medians and industrial plant site turf at max. 1 lb./a.i. > per acre; mosquito control; fire ants mound treatment; non-structural wood treatment); • Agricultural uses without new Restricted Re-entry Intervals (REIs).
December 31, 2002	No spot or local treatment for termites allowed.
December 31, 2004	EPA rules on adequacy of June 30, 2004 pre-construction data: no existing stocks of MU for formulation of End Use for termite (unless allowed for pre-construction per data).
December 31, 2005	No distribution, sale or use of End Use pre-construction termite use (unless allowed for pre-construction data).



Chlorpyrifos Revised Risk Assessment and Agreement with Registrants

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Action and Rationale

EPA has released its revised risk assessment and announced an agreement with registrants to eliminate and phase out certain uses of the organophosphate pesticide chlorpyrifos. Also known as Dursban, Lorsban, and other trade names, chlorpyrifos is one of the most widely-used insecticides in the U.S., both in agriculture and in and around the home.

The Food Quality Protection Act, enacted in 1996, sets a more stringent safety standard for most pesticides and offers special protection for children. In meeting the tough safety standard, EPA believes it can do a better job of protecting children and others by further reducing exposure to chlorpyrifos, and providing the increased margins of safety now mandated by federal law. These use modifications also will improve safety for workers who apply chlorpyrifos and for the environment.

Risk Mitigation

EPA and the registrants have agreed to the following modifications:

- **Reducing Food Risks...** The agreement will expeditiously address food uses posing the greatest risks to children. It decreases the use of chlorpyrifos on apples, terminating or canceling all post-bloom applications, and cancels the use on tomatoes. EPA will also propose to 1) lower the tolerance or maximum residue limit on apples to reflect this change in use, 2) revoke the tolerance on tomatoes, and 3) lower the tolerance on grapes to a level that will allow for

dormant applications (the only use allowed domestically), but not foliar applications typically made in foreign countries on grapes that are imported into the U.S. These actions will reduce acute dietary risk by 75 percent, effectively eliminating dietary risk concerns for children and others.

- **Reducing Residential Risks...** About 50 percent of chlorpyrifos is used in and around the home. The agreement will cancel and phase out nearly all indoor and outdoor residential uses. It effectively eliminates the use of chlorpyrifos by homeowners, limiting use to certified, professional, or agricultural applicators. Those uses that pose the most immediate risks to children, including home lawn, indoor crack and crevice treatments, and whole house "post-construction" termiticide treatments, will be canceled first. Spot and local post-construction and pre-construction termiticide uses will be phased out over the next several years.

- **Reducing Drinking Water Risks...** The actions on residential uses also will reduce exposure to chlorpyrifos through drinking water, since residential applications are potentially a major source of drinking water contamination.

- **Reducing Non-Residential Risks...** Chlorpyrifos use in schools, parks, and other settings where children may be exposed will be canceled. Only use in some limited commercial settings, like warehouses, ship holds and railroad boxcars, may continue.

- **Reducing Worker Risks...** Risks to

workers who apply chlorpyrifos also are of concern. The agreement will help mitigate worker risks by implementing Restricted Entry Intervals (REIs) for agricultural uses. By August 1, 2000, chlorpyrifos registrants also will be proposing lower application rates, lower frequencies of treatment, and longer time periods between applications and harvest (pre-harvest intervals) for some agricultural uses. These and other measures to reduce both worker and ecological risks will be discussed further in consultation with stakeholders as EPA develops an interim reregistration eligibility decision for chlorpyrifos.

• **Protecting Public Health Uses...** Under the agreement, public health uses including applications to fire ant mounds and ultra low volume applications for mosquito control will be allowed to continue. These applications do not pose risks of concern and provide important public health benefits.

46 • **Supporting Low-Risk Uses...** The agreement allows several other non-agricultural uses to continue, with appropriate risk mitigation. Golf course applications, for example, may continue with application rates reduced by 75 percent. Low risk uses like containerized baits in child resistant packaging, and non-structural wood treatments such as treatments of utility poles and fenceposts, will not be affected by the agreement.

Phased In Approach

The agreement phases in the various restrictions and cancellations to address higher risk uses of chlorpyrifos first. Because much of the risk reduction involves increasing margins of safety, it is reasonable to focus first on the uses that achieve the greatest risk reduction for children. Allowing other uses to continue for a specific period of time will help ensure that appropriate alternatives are available for a reasonable and orderly transition.

Provisions of the Agreement and Associated EPA Actions

Food Uses		
Crop	Mitigation Measures	Effective Dates
Apples	Production of chlorpyrifos products labeled for post-bloom application is prohibited (only production for pre-bloom, dormant application is allowed) Post-bloom use is prohibited Tolerance will be lowered	August - September 2000 Stop use (use prohibited) as of 12-31-00
Tomatoes	Production of products for tomato use is prohibited Use will be canceled Tolerances will be revoked	August - September 2000 Stop use as of 12-31-00
Grapes	Tolerance will be lowered	

Food Uses

<p>All Agricultural Uses</p>	<p>Classify new end-use products for restricted use or package in large containers</p> <p>New end-use products must bear revised Restricted Entry Intervals (REIs)</p>	<p>As of 12-1-00</p> <p>As of 12-1-00</p>
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Home Uses

Site	Mitigation Measures	Effective Dates
<p>Home lawn and most other outdoor uses</p>	<p>Classify new end-use products for restricted use or package in large containers (except baits in child resistant packaging)</p> <p>Use will be canceled</p>	<p>As of 12-1-00</p> <p>Stop formulation 12-1-00 Formulators stop sale 2-1-01 Retailers stop sale 12-31-01</p>
<p>Crack and crevice and most other indoor uses</p>	<p>Classify new end-use products for restricted use or package in large containers</p> <p>Use will be canceled</p>	<p>As of 12-1-00</p> <p>Stop formulation 12-1-00 Formulators stop sale 2-1-01 Retailers stop sale 12-31-01</p>
<p>Termiticides</p> <ul style="list-style-type: none"> • Full barrier (whole house) post-construction use • Spot and local post-construction use • Pre-construction use 	<p>Classify new products for restricted use or package in large containers</p> <p>Limit use to 0.5% solution</p> <p>Use will be canceled</p> <p>Use will be canceled</p> <p>Use will be canceled</p>	<p>As of 12-1-00</p> <p>In label directions as of 12-1-00</p> <p>Stop formulation 12-1-00 Formulators stop sale 2-1-01 Retailers stop sale 12-31-01</p> <p>Stop formulation 12-1-00 unless label has stop use date of 12-31-02</p> <p>Stop production 12-31-04 Stop use 12-31-05</p>

Non-Residential Uses

Site	Mitigation Measures	Effective Dates
<p>Indoor areas where children could be exposed (such as schools)</p>	<p>Uses will be canceled</p>	<p>Stop formulation 12-1-00 Formulators stop sale 2-1-01 Retailers stop sale 12-31-01</p>
<p>Outdoor areas where children could be exposed (such as parks)</p>	<p>Uses will be canceled</p>	<p>Stop formulation 12-1-00 Formulators stop sale 2-1-01 Retailers stop sale 12-31-01</p>

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Non-Agricultural Uses that Will Remain

Site	Mitigation Measures	Effective Dates
(a) Residential use of containerized baits	Already in child resistant packaging	(Use allowed to continue)
(b) Indoor areas where children will not be exposed, including only ship holds, railroad boxcars, industrial plants, manufacturing plants, or food processing plants		New end-use product labels must reflect only these uses as of 12-1-00
(c) Outdoor areas where children will not be exposed, including only: <ul style="list-style-type: none"> • Golf courses • Road medians • Industrial plant sites • Non-structural wood treatments including fenceposts, utility poles, railroad ties, landscape timbers, logs, pallets, wooden containers, poles, posts, and processed wood products 	<p>Reduce application rate from 4 lbs/acre to 1 lb/acre</p> <p>Reduce maximum application rate to 1 lb ai/acre</p> <p>Reduce maximum application rate to 1 lb ai/acre</p> <p>(Continue at current rate)</p>	New end-use product labels must reflect only these uses as of 12-1-00
(d) Public health uses <i>for fire ant mound control</i> <ul style="list-style-type: none"> • Fire ant mounds (drench and granular treatment) • Mosquito control 	<p>For professional use only</p> <p>For professional use only</p>	

For Additional Information

For additional materials on the chlorpyrifos decision, or for information on other aspects of the Agency's pesticide regulatory program, contact EPA's Office of Pesticide Programs at (703) 305-5017, or visit our web site, www.epa.gov/pesticides.

For information on pesticides and their toxicity, contact the National Pesticide Telecommunications Network at 1-800-858-7378.

Comparison of Recently Established Safety Standards for Chlorpyrifos

The following table compares safety standards recently established by various regulatory authorities around the world. Note that safety standards set by other regulatory authorities are up to 300 times greater than that recently established by the U.S. Environmental Protection Agency (EPA). The differences between standards are based on (1) use of available human data, (2) endpoint selection, and (3) application of an additional 10X safety factor by U.S. EPA.

	U.S. EPA	WHO/FAO	California	Australia
Acute Safety Standard	0.0005 mg/kg/d	0.1 mg/kg/d	0.1 mg/kg/d	0.01 mg/kg/d
Endpoint¹	plasma ChEI (rat)	RBC AchEI (human)	RBC AchEI (human)	plasma ChEI (human)
From EPA²		<i>200X higher</i>	<i>200X higher</i>	<i>20X higher</i>
Chronic Safety Standard	0.00003 mg/kg/d	0.01 mg/kg/d	0.01 mg/kg/d	0.003 mg/kg/d
Endpoint¹	RBC AchEI (dog)	RBC AchEI (human) Brain AchEI (rat) Brain AchEI (dog) Brain AchEI (mouse)	Brain AchEI (dog)	plasma ChEI (human)
From EPA²		<i>300X higher</i>	<i>300X higher</i>	<i>100X higher</i>

¹ Endpoint refers to the "effect" which serves as the basis for the safety standard where "ChEI" is butyrylcholinesterase inhibition and "AchEI" is acetylcholinesterase inhibition.

² From EPA means the magnitude of the difference in a safety standard compared to that set by U.S. EPA.

EPA
 Office of Pesticide Programs
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Chlorpyrifos Summary

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- Food uses for chlorpyrifos are: cranberries, strawberries, citrus, apples, figs, pears, nectarines, cherries, peaches, plums, grapes, almonds, pecans, walnuts, onions, peppers, kale, broccoli, brussels sprouts, cabbage, cauliflower, collards, cucurbits, asparagus, roots/tubers, corn, tomatoes, lentils, beans, peas, sorghum, tobacco, wheat, alfalfa, peanuts, soybeans, sunflower, cotton, sugar beets, mint, and bananas.
- Chlorpyrifos is also used as a termiticide; mosquitocide; a treatment for lawns, turf and ornamentals; an indoor crack and crevice and spot treatment; as a pet collar; as a treatment for pasture, woodland and lots/farmsteads; and as a cattle eartag.
- Use of chlorpyrifos in and around homes and in non-residential settings will be eliminated or phased-out by the chlorpyrifos manufacturers. Further, apple use will be restricted and use on tomatoes will be eliminated.
- Chlorpyrifos is not currently a restricted use pesticide. It is applied by the following methods: aerial, chemigation, groundboom, tractor-drawn granular spreader, airblast sprayer, low & high pressure hand wands, hydraulic hand-held sprayer, shaker can, bulbous duster, belly grinder, push-type spreader, large tank sprayer, compressed air sprayer, hose-end sprayer, aerosol sprayer, hand, pet collars and eartags.
- An estimated twenty to twenty-four million pounds of chlorpyrifos are expected to be applied annually. Approximately 50% of the use of chlorpyrifos is in agricultural settings and 50% of the use is in non-agricultural settings. An estimated 24% of all use of chlorpyrifos is as a termiticide.
- Mitigation is expected to reduce the total use of chlorpyrifos by as much as 50% when fully implemented based on available use data from the late 1990's.
- Chlorpyrifos can cause cholinesterase inhibition in humans; that is, it can overstimulate the nervous system causing nausea, dizziness, confusion, and at high exposures, respiratory paralysis, and death.

Dietary risk from food is below levels of concern based on risk mitigation.

- The acute and chronic risk assessments are highly refined using USDA Pesticide Data Program (PDP) data and FDA monitoring data that reflects actual use of pesticides for most commodities.

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• Prior to mitigation, at the 99.9th percentile exposure there were acute risks of concern for the most exposed sensitive population sub-groups, consisting of all infants, children 1-6 years old, children 7-12 years old and females.

- Use of chlorpyrifos on apples, tomatoes and grapes have been mitigated to address acute dietary risks.
- After mitigation, at the 99.9th percentile, acute risks are not of concern for the most highly exposed population sub-group, children 1-6 years old.
- Chronic dietary risk is not of concern.

Residential risks have been mitigated.

- Prior to mitigation, post application re-entry risks and mixer/loader/applicator risks for residents are of concern for all exposure scenarios. These risk estimates are based on chlorpyrifos-specific studies supplemented by the Agency's SOPs for estimating residential exposure.
- To address residential risks, use of chlorpyrifos in and around homes and in non-residential settings will be eliminated or phased-out by the chlorpyrifos manufacturers.
- After mitigation residential risks are not of concern.

Worker risks are moderate and have been mitigated in some cases.

- For mixers, loaders, and applicators, risks for some exposure scenarios, including residential applications, are of concern even with maximum Personal Protection Equipment (PPE)/engineering controls, using data from chlorpyrifos-specific studies and the Pesticide Handlers Exposure Database.
- Restricted Entry Intervals (REIs) ranging from 1 to 10 days (with most of them being 1 day) would be necessary for various crops and activities to address post application re-entry risks. Typical labels currently require 12-24 hour REIs.
- As part of the mitigation, the chlorpyrifos registrants have agreed to voluntarily place the new REIs on all agricultural products. This will address post application worker risks.

Drinking water risk is below the levels of concern.

- A drinking water assessment that relies heavily on monitoring data determined that acute and chronic exposure from drinking water is not of concern based on the mitigation. Additionally, the voluntary mitigation mentioned earlier will mitigate drinking water exposures.
- Some localized applications of the subterranean termiticide use

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incidents from 1992-1997. In some instances, high levels of contamination have occurred. The risk assessment using high-end concentrations from these incidents conservatively estimates risks in these localized areas as very high. Incidents of this kind have been decreasing steadily since the issuance of the PR Notice on termiticides in 1996.

Aggregate risk is not of concern based on risk mitigation.

- The short-term and intermediate-term aggregate risks do not exceed the Agency's level of concern. Chronic aggregate risks do not raise a concern when all of the uncertainties and mitigation are considered.

Ecological risks are moderate.

- The risk assessment indicates that risk to birds, fish and mammals are high and that risks to aquatic invertebrates is very high.
 - The mitigation of residential uses is expected to have some beneficial impact on risks to both aquatic and terrestrial organisms.
-

PRESS RELEASE

**Dow AgroSciences Announces Changes
in Use of Chlorpyrifos Products**

Indianapolis -- Dow AgroSciences, a recognized leader in the pest management industry, has reached agreement with the U.S. Environmental Protection Agency (EPA) on changes in the use of insecticides containing chlorpyrifos, in alignment with the Clinton Administration's stated goal of reducing the potential exposure of children to all pesticides.

"We really care about the safety of children and their families," said Elin Miller, vice president of the Dow AgroSciences urban pest business. "We are in the business of helping people by managing pests that harm children, and we are in this business for the long haul."

In its ongoing implementation of the Food Quality Protection Act of 1996 (FQPA), the EPA has demonstrated that it intends to apply standards far more restrictive than those historically established by the scientific community and accepted by the EPA and other regulatory bodies around the world.

"FQPA has fundamentally changed the way in which pesticides are regulated in the United States," said Miller. "Unfortunately, we found that continued efforts to retain certain uses of chlorpyrifos in the U.S. no longer made business sense in the current regulatory environment. Under these new circumstances, we found we had to make some very difficult decisions.

"Because of FQPA, the rules have changed," Miller added, "but the safety of chlorpyrifos hasn't. We ultimately felt that we had to reach an agreement with EPA for the use of these products in the U.S., but this does not change our conviction in the safety of chlorpyrifos for all labeled uses."

The agreement that Dow AgroSciences is announcing includes a voluntary cancellation of most in-and-around-the-home uses of chlorpyrifos in the U.S. including use of the product as a full-barrier termiticide treatment in existing residential structures (post-construction). Use of products affected by this agreement will be allowed until existing stocks are depleted.

Use of chlorpyrifos in the U.S. as a termiticide for spot and local treatment will be allowed until December 31, 2002. Chlorpyrifos will remain available in the U.S. for uses as a termiticide for new residential construction (pre-treat) until December 31, 2005.

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This date may be extended, however, based on the results of an exposure study specific to this application. 40

Retail sale of chlorpyrifos products in the U.S. will be allowed until December 31, 2001. Chlorpyrifos will remain available for various U.S. nonresidential uses such as golf courses and ornamental nurseries as well as for all U.S. crop uses except tomatoes.

The agreement includes refinements in agricultural applications that result in a reduction of chlorpyrifos residues in the U.S. on apples and grapes.

This agreement is specific to the U.S. sale and use of chlorpyrifos.

Chlorpyrifos products have been on the market for more than 30 years. No pest control product has been more thoroughly studied. The latest World Health Organization/Food and Agriculture Organization, conducted last year, supported the safety of the product for all its labeled uses.

More than 3,600 studies and reports have been conducted examining critical aspects of chlorpyrifos products as they relate to health and safety. Taken together, these reports and studies show that currently labeled uses of chlorpyrifos products provide wide margins of safety for both adults and children.

Chlorpyrifos is used to protect virtually every major crop grown in the U.S. from insect damage. It has been used in and around millions of homes each year to safeguard families and pets from dangerous pests like cockroaches, ticks, fleas, termites, spiders and fire ants.

Dow AgroSciences will continue to support chlorpyrifos products for many critical uses of vital importance to its customers. Dow AgroSciences also provides innovative, reduced-risk insect control products like the Sentricon* *Termite Colony Elimination System* and spinosad insect control, which was a recent recipient of EPA's Presidential Green Chemistry Award.

*Trademark of Dow AgroSciences LLC

Contact: Garry Hamlin, Dow AgroSciences (317) 337-4799

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What should I do with chlorpyrifos products I have in my home now?

CHANGES IN THE U.S. USE OF CHLORPYRIFOS UNDER THE FOOD QUALITY PROTECTION ACT

Questions and Answers

What is chlorpyrifos?

Chlorpyrifos is one of the most widely used active ingredients for pest control products in the world, largely due both to the economical control they offer against a wide spectrum of pests and to the wide margins of safety provided when the products are used according to label directions. Used as the active ingredient in more than 800 products, chlorpyrifos has been extensively studied and has been on the market for more than 30 years. Chlorpyrifos products are used around the world for both agricultural and nonagricultural applications. They are registered in more than 80 countries and frequently sold under the tradenames Dursban* and Lorsban* insecticide.

What Dow AgroSciences products contain chlorpyrifos?

Chlorpyrifos is the active ingredient in Dursban*, Lorsban*, Empire*, Equity* and Lock-On* pest control products.

What benefits do chlorpyrifos products offer?

Chlorpyrifos products protect virtually every major U.S. crop against damage from a wide spectrum of insects. They are also used in and around millions of homes each year to safeguard families and pets from dangerous pests like cockroaches, ticks, fleas, termites, spiders and fire ants.

What is the Food Quality Protection Act?

The Food Quality Protection Act of 1996 is a law that requires the U.S. Environmental Protection Agency to evaluate by 2006 all pest management products in light of stringent requirements intended to even further reduce exposures to pesticides, particularly exposures to children. The EPA has interpreted this law to require standards far more stringent than those previously used within the U.S. and more restrictive than those currently used by the World Health Organization, the State of California and regulators in other developed nations. The organophosphate insecticides are one of the first classes of pesticide active ingredients to be reviewed under the Food Quality Protection Act. Chlorpyrifos, the active ingredient in Dursban and Lorsban insecticides, is an organophosphate insecticide. The EPA's implementation of the Food Quality Protection Act has resulted in changes in the use of a number of other organophosphate pest control products, prior to this agreement for chlorpyrifos.

What changes in the U.S. use of chlorpyrifos products will occur under the Food Quality Protection Act?

As a result of the U.S. Environmental Protection Agency's implementation of the Food Quality Protection Act, registrants of chlorpyrifos have agreed to several changes to the existing uses of chlorpyrifos products in the United States, especially how the product can be used in residential settings. Dow AgroSciences and these other registrants have agreed to a voluntary cancellation of most in-and-around-the-home uses of chlorpyrifos in the United States, including use of the product as a full-barrier termiticide treatment in

existing structures (post-construction). Use of products affected by this agreement will be allowed until existing stocks are depleted. Use of chlorpyrifos in the U.S. as a termiticide for spot and local treatment will be allowed until December 31, 2002. Chlorpyrifos will remain available in the U.S. for use as a termiticide for new construction (pre-treat) until December 31, 2005. This date may be extended, however, based on the results of an exposure study specific to this application.

What U.S. uses of chlorpyrifos products remain under this agreement?

Under the agreement, chlorpyrifos will remain available for various U.S. nonresidential uses, such as golf courses, ornamental nurseries, professional use against fire ants as well as for all U.S. crop uses except tomatoes.

Has chlorpyrifos been thoroughly researched and tested?

Chlorpyrifos, the active ingredient in Dursban and Lorsban insecticides, has been widely used and extensively studied for three decades, and manufacturers continue to update those tests with new technology each year. Its worldwide registrations are supported by an extensive proprietary and published database. More than 3,600 studies and reports have been conducted examining the uses and impacts of chlorpyrifos on human health and the environment, including data reviews of its environmental fate, ecotoxicology, neurotoxicity and dietary exposure, plus expert panel reviews assessing the compound's human health and ecological profile. No other pest control product has been researched more thoroughly.

Does coming into contact with chlorpyrifos products pose a risk?

Consumer exposure from labeled use of chlorpyrifos products provides wide margins of safety for both adults and children. These exposures are far too low to result in harmful effects. Serious misuse of chlorpyrifos (e.g. attempted suicide by drinking the product) can result in adverse effects and, in the most extreme cases, death. Always read the label carefully and follow instructions when using chlorpyrifos or any other pesticide product.

If the U.S. Environmental Protection Agency's objective is to reduce exposures to chlorpyrifos, why aren't these products being recalled and why is the EPA allowing preconstruction termite applications over the next four years?

The U.S. Environmental Protection Agency is not taking the position that the labeled use of these products poses an imminent hazard. The Agency is choosing to widen the existing margins of safety on pest management products like chlorpyrifos. However, all past and current labeled uses of chlorpyrifos products already provide wide margins of safety for both adults and children.

I've had a chlorpyrifos product applied in my home. Should I be concerned?

No. Labeled use of chlorpyrifos products has been shown by extensive research and 30 years of use to offer effective pest control while providing wide margins of safety for both adults and children. These products are registered in virtually every developed nation around the world. No pest control product has been more thoroughly studied.

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What should I do with chlorpyrifos products I have in my home now?

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Use them with confidence, according to the label. While the regulatory standards have changed, the safety profile of chlorpyrifos has not. Use of products affected by this agreement will be allowed until existing stocks are depleted. Using chlorpyrifos products as directed on the product label will deliver effective, economical pest control and provide wide margins of safety for all labeled uses.

Chlorpyrifos (Dursban*/Lorsban*) Products

Chlorpyrifos is one of the most extensively studied and widely used pest control products in the world.

PROVEN SAFETY AND QUALITY

- Used as directed, chlorpyrifos products are safe for use around adults and children.
- More than 3,600 studies and reports have been conducted examining critical aspects of chlorpyrifos products as they relate to health and safety. Taken together, these reports and studies affirm that chlorpyrifos products, when used as directed, provide wide margins of safety for both adults and children.
- In terms of human health and safety, no pest control product has been more thoroughly studied.

WORLDWIDE ACCEPTANCE

- Chlorpyrifos is one of the most widely used active ingredients for pest control products in the world.
- First registered in 1965, chlorpyrifos products have been on the market for more than 30 years.
- Trade names frequently used for these products are Dursban and Lorsban insecticides. However, chlorpyrifos is used in more than 800 pest control products, some of which are available in hardware stores.
- Chlorpyrifos products are registered in more than 80 countries around the world, including most developed nations.

AGRICULTURAL USES

- Chlorpyrifos products are used to protect virtually every major crop grown in the U.S. from damage caused by a wide spectrum of insects.
- U.S. crops on which chlorpyrifos products are registered for use include: alfalfa, almonds, apples, asparagus, broccoli, Brussels sprouts, cabbage,

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cauliflower, cherries, citrus, collards, corn, cotton, cranberries, cucurbits, currants, cut flowers, dry beans, durum, grain sorghum, grapes, grass seed, greenhouses, hazelnuts, kale, milo, mustard, onions, pears, peaches, peanuts, pecans, peppermint, peppers, radishes, snap beans, sod farms, soybeans, spearmint, strawberries, sugarbeets, sunflowers, sweet potatoes, tobacco, tomatoes, tree nurseries, turnips, walnuts and wheat.

NONAGRICULTURAL USES

- Chlorpyrifos products are also used against pests in a wide variety of non-agricultural applications. They have been used in and around millions of homes each year to safeguard families and pets from dangerous pests like cockroaches, ticks, fleas, termites, spiders and fire ants.
- Nonagricultural applications for which chlorpyrifos products are currently registered in the U.S. include: fire ant control, golf courses, landscaping, lawn care, ornamental trees, general indoor/outdoor pest control, termite control and turf.

Dow AgroSciences

- Dow AgroSciences, a wholly owned subsidiary of The Dow Chemical Company, is the primary manufacturer of chlorpyrifos in the U.S.
- Chlorpyrifos is also manufactured by other companies in Denmark, Israel and India.
- *Trademark of Dow AgroSciences

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Reregistration Commences for Chlorpyrifos and Chlorpyrifos-methyl in the United States

All pesticides sold in the United States must be approved and registered by the Environmental Protection Agency (EPA). Because of advancements in science, United States law requires that all pesticides registered before November 1, 1984, be "re-registered" to ensure they meet today's safety standards and requirements.

New dimensions were added to the EPA's pesticide reregistration program in 1996, when laws governing pesticides were changed by the passage of the Food Quality Protection Act (FQPA). These changes included a new, more stringent, safety standard that must be applied to all pesticides used on foods.

The EPA has selected the organophosphate insecticides to be one of the first groups of pesticides to be reevaluated under the new safety standards of FQPA. Chlorpyrifos (the active ingredient in Dursban* and Lorsban* insecticides) and chlorpyrifos-methyl (the active ingredient in Reldan* insecticide) are organophosphate insecticides.

The EPA recently completed *preliminary* risk assessments for chlorpyrifos and chlorpyrifos-methyl under its reregistration program. During the reregistration process, preliminary risk assessments are revised and refined to make them more comprehensive and realistic. The EPA explicitly "*cautions against premature conclusions based on these preliminary assessments and against any use of the information contained in these documents out of their full context.*"

Review of the preliminary risk assessments for chlorpyrifos and chlorpyrifos-methyl by Dow AgroSciences revealed numerous errors and omission of critical data that significantly skew the results. Central to both of EPA's assessments are policy proposals that change the longstanding basis of regulation of chlorpyrifos and chlorpyrifos-methyl, significantly reducing the acceptable levels of exposure (i.e., the "risk cup"). Because proposed changes are policy-based, rather than scientifically determined, estimates of risk contained in these documents are artificially inflated.

EPA's proposed policy-based "risk cup" values are significantly lower than the scientifically derived regulatory values used by most international regulatory bodies, including the European Union and the World Health Organization.

Revisions to the EPA's preliminary risk assessments submitted by Dow AgroSciences show that chlorpyrifos and chlorpyrifos-methyl products have wide margins of safety to protect users and consumers, including children, when used in accordance with label instructions.

Dow AgroSciences looks forward to working with the EPA throughout the duration of the reregistration process to assist in the development of more realistic risk assessments and the successful reregistration of these valuable pest control products.

*Trademark of Dow AgroSciences LLC

What The U.S. Environmental Protection Agency Says About Chlorpyrifos Residues In Food And Water

Excerpts From Recently Released EPA Documents

Is it safe to eat food that has been treated with chlorpyrifos?

"Yes. Food treated prior to these restrictions still provides a considerable margin of safety to consumers. This action simply makes it stronger. The health benefits of a varied diet high in fresh fruits and vegetables outweigh the risk of pesticide residues anticipated on treated fruit. Parents should continue to feed their children a balanced and nutritious diet rich in fruits and vegetables." (*"Questions and Answers: Chlorpyrifos Revised Risk Assessment and Risk Mitigation Measures."* U.S. EPA, June 8, 2000, p. 3.)

"The chronic dietary risk (food) does not exceed the Agency's level of concern for the general U.S. population and all subgroups." (*"Overview of Chlorpyrifos Revised Risk Assessment."* U.S. EPA, p. 6.)

Drinking Water

"Monitoring data confirm that chlorpyrifos does not impact groundwater." (U.S. EPA Technical Briefing, Washington, D.C., June 8, 2000, slide 123.)

"There are no acute concerns for residues in drinking water." (U.S. EPA Technical Briefing, Washington, D.C., June 8, 2000, slide 73.)

"Environmentally expected concentrations [are] highly conservative for majority of U.S. population." (U.S. EPA Technical Briefing, Washington, D.C., June 8, 2000, slide 75.)

What The U.S. Environmental Protection Agency Says About Residential Use Of Chlorpyrifos (Dursban* insecticide)

Excerpts From Recently Released EPA Documents -62-

"My house has just been treated for termites or other insects. What precautions should I take? ...Should I be concerned if my home, school or office was treated with chlorpyrifos?"

"...[S]hort-term use of these products used according to label directions does not present an imminent risk. If the building has been treated in the last several years, low levels of the pesticide used may be found. However, these low air-concentration levels generally would not warrant corrective actions beyond those suggested for improving indoor air quality." (*"Questions and Answers: Chlorpyrifos Revised Risk Assessment and Risk Mitigation Measures."* U.S. EPA, June 8, 2000, p. 4.)

"EPA advises consumers that short-term use of these products according to label instructions does not pose an imminent risk." (*"Clinton-Gore Administration Acts to Eliminate Major Uses of the Pesticide Dursban To Protect Children and Public Health."* U.S. EPA, Washington, D.C., press release, June 8, 2000.)

~~On residential post-application risks of chlorpyrifos products for termite control~~

"In summary, it is important to bear in mind that FQPA demands that stringent safety standards be used to assess residential uses, including termiticide uses. Although not all of the risk estimates achieve a margin of exposure of 1,000, the Agency believes that considering the uncertainties in the assessment (the conservative assumptions, the 1,000-fold safety factor, in conjunction with the additional three- to ten-fold cushion between the effect level and the no-observable-effect level) as well as the mitigation, this use does not raise a concern." (*"Overview of Chlorpyrifos Revised Risk Assessment."* U.S. EPA, June 3, 2000, p. 14.)

~~What should I do with existing chlorpyrifos products?~~

"It is legal to purchase and use chlorpyrifos products according to label directions and precautions. Use of these products according to label directions does not pose an imminent hazard. Consumers who use the product should take special care to always read and follow the label." (*"Questions and Answers: Chlorpyrifos Revised Risk Assessment and Risk Mitigation Measures."* U.S. EPA, June 8, 2000, p. 6.)

~~On risks from residential use of chlorpyrifos products for termite control during the mitigation period~~

"Acute and short-term aggregate risks are not of concern. Chronic aggregate risks with all uncertainties and mitigation considered do not raise a concern." (*U.S. EPA Technical Briefing, Washington, D.C.; June 8, 2000, slide 168.*)

*Trademark of Dow AgroSciences LLC

On whether chlorpyrifos products pose a greater risk than other organophosphate insecticides

"[The] rate of [residential] exposure [incidents] [are] comparable to other organophosphates.... Most of these incidents are due to misuse." (U.S. EPA Technical Briefing, Washington, D.C., June 8, 2000, slide 123.)

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पत्र सं./No. 20-31/2000 - CIR

भारत सरकार
GOVERNMENT OF INDIA
कृषि मंत्रालय
MINISTRY OF AGRICULTURE
(कृषि एवं सहकारिता विभाग)
(DEPARTMENT OF AGRICULTURE AND CO-OPERATION)
वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय,
DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE
एन.एच.4, फरीदाबाद (हरियाणा)-121001
N.H.IV, FARIDABAD (HARYANA)-121001

दिनांक/Dated : 23.10.2000

To

As per list enclosed.

Subject: Minutes of the first meeting of the Expert Group under the Chairpersonship of Dr. (Mrs) S.B. I Add. Prof., Deptt. of Pharmacology, AIIMS, New Delhi held on 20.10.2000 at CIL, Faridabad to review the status of Chorpyriphos in the country.

Sir,

I have the honour to enclosed herewith a copy of minutes of the above mentioned meeting. You are requested to take further necessary action as stipulated in the minutes enclosed herewith.

Yours faithful,

S.Kulshrestha

(S.Kulshrestha
Joint Director(Med.)
Member-Secretary

Minutes of the first meeting of the Expert Group under the chairpersonship of Dr.(Mrs.) S.B.Lall, Addl.Prof.,Pharm.,Deptt. of Pharmacology, AIIMS, New Delhi to review the use of Chlorpyriphos in the country held on 20.10.2000 at 11 A.M. in Conference Hall of Central Insecticides Laboratory, Faridabad.

The first meeting of the Expert Group under the chairpersonship of Dr.(Mrs.) S.B.Lall, Addl.Prof.,Deptt. of Pharmacology, AIIMS, New Delhi to review the use of Chlorpyriphos in the country was held on 20.10.2000 at 11 A.M. in Conference Hall of Central Insecticides Laboratory, Faridabad. The list of participants is at Annexure. Dr.(Mrs.) Usha Gupta, Prof.,Deptt. of Pharmacology, Maulana Azad Medical College, New Delhi, Dr. S.R. Gupta, ADG(PFA),Ministry of Health & Family Welfare,New Delhi and Director, Haffkin Institute and representative from Ministry of Environment and Forests could not participate. However, Shri Raj Kumar, representative from PMFAI who is not in the composition of the Group participated in the meeting.

At the outset of the meeting, the Chairperson welcomed the participants and requested Dr.(Mrs.) S.Kulshrestha, Member-Secretary to give background of the constitution of the Committee and take up the agenda items one by one. The Member-Secretary gave the background of the constitution of the Committee to review the use of chlorpyriphos in the country and apprised the members that the report of the Committee is to be submitted to the Deptt. of Agriculture & Cooperation within two months time. Thereafter, the agenda was taken up for discussion.

Dr. Ajit Kumar, representative of ICOPA made a presentation regarding the basis of decision of US EPA for banning home uses of Chlorpyriphos in their country. While making the presentation he mentioned that the 52% of Chlorpyriphos is being used in non-agricultural areas in USA as against the quantity of only 8% in India. He emphasised that the ban is a part of an ongoing effort to implement the Food Quality Protection Act of 1996 which requires a systematic Government review to all pesticides to ensure that they meet tighter standards with the goal of protecting children foremost and thus increased the safety factor by 100 fold. He also mentioned that during its review by US EPA, the product has also been reviewed by WHO,UK and EC countries and these agencies/countries did not recommend the lowering down of the existing RADI of Chlorpyriphos. Dr. O.P. Dubey, ADG, ICAR informed that no resistance against Chlorpyriphos in agricultural pest has been reported in the country. Further, he stated that in the studies carried out at Raturi Centre of All India Coordinated Project on Pesticide Residue, no residue of Chlorpyriphos in grapes was detected and more intensive studies are in progress in different Centres. Shri D. Srinath, representative of ICOPA informed that the use of Chlorpyriphos for termite control in pre and post construction of buildings is picking up after ban of Chlordane and Heptachlor. Dr. Y.Singh, Scientist, Central Building Research Institute, Roorkee also supported views of Shri D. Srinath that Chlorpyriphos is effective as termiticide for protecting the building.

The chairperson emphasised that there is a need to collect information with regard to the studies undertaken in our country to assess the health effects of Chlorpyrifos during its use as termiticide in pre and post construction of buildings.

The members deliberated on the parameters on which information are to be collected and compiled to fulfill the mandate assigned to the Committee and finalised the following parameters:-

1. Chemistry
2. Global registration status
3. Registration status in India
4. Global production/consumption of Chlorpyrifos
5. Production/consumption of chlorpyrifos in India
6. Global use status of Chlorpyrifos
7. Uses of Chlorpyrifos in India as approved under the Insecticides Act, 1968.
8. Ongoing practices by the Pest Control Operators for home usage of Chlorpyrifos
9. Toxicity of Chlorpyrifos
 - (a) Acute toxicity
 - (b) Long-term and other toxicity
 - (c) Environmental toxicity
 - (d) Toxicity aspects for safe re-entry period.
10. Countries where Chlorpyrifos is banned/severely restricted.
11. Reason for their ban/restriction and their relevance to Indian scenario.
12. Alternatives available globally.
13. Alternatives available under the Insecticides Act for use in India.

The Member-Secretary informed that some of the information on chemistry, toxicity and bio-efficacy and approved uses of Chlorpyrifos in India and its alternatives and production consumption has already been collected.

Further, it has been decided that data on the parameters as indicated at Sl.Nos. 1 & 9 will be collected by Dr.(Mrs.) S.Kulshrestha; on Sl.Nos. 2,4,6,10, 11 & 12 by ICPA; on Sl.Nos.3,5,7 & 13 by Dr.Brajendra Singh Entomologist(Insecticides) and on Sl.No. 8 by Indian Pest Control Operators Association. The information/data on these parameters shall be collected by respective members and provided to Dr.(Mrs.) S.Kulshrestha, Member-Secretary by 15th of November, 2000. After receipt of the requisite information, Member-Secretary may convene a meeting at the convenience of the Chairperson in the third week of November, 2000.

The meeting ended with a vote of thanks to the Chair.

List of Participants

1. Dr. (Mrs.) S.B. Lall, Chairperson
Addl. Prof., Pharm.,
Deptt. of Pharmacology,
AIIMS, New Delhi
2. Dr. O.P. Dubey,
ADG(PP), ICAR,
Kishi Bhavan,
New Delhi
3. Dr. Brajendra Singh,
Entomologist(I),
Dte. of PPQ&S, Faridabad
4. Dr. (Mrs.) S. Kulshrestha,
JD(M&P), Dte. of PPQ&S,
Faridabad.
5. Shri D. Srinath,
Indian Crop Protection Association(ICPA)
6. Shri Alok Moitra,
ICPA
7. Dr. A.V. Dhuri,
ICPA
8. Shri Ajit Kumar,
ICPA
9. Shri P. Roy Chowdhury,
ICPA
10. Shri C.V.G. Menon,
Pesticide Association of India
11. Shri Y. Singh,
Scientist, CBRI,
Roorkee

तार का पता: प्रोटेक्शन
Telegram : PROTECTION
टेलीफोन/Telephone :

पत्र सं./No. 20-31/2000-CIR II

भारत सरकार
GOVERNMENT OF INDIA
कृषि मंत्रालय
MINISTRY OF AGRICULTURE
(कृषि एवं सहकारिता विभाग)
(DEPARTMENT OF AGRICULTURE AND CO-OPERATION)
वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय,
DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE
एन.एच.4, फरीदाबाद (हरियाणा)-121001
NH-IV, FARIDABAD (HARYANA)-121001

दिनांक/Dated: 5.12.2000

To

As per list enclosed.

Subject:- Second meeting to review the use of Chlorpyrifos
in the country- reg.

Sir,

In continuation of this Directorate's letter of even number dated 23.10.2000, it is to inform you, that with the approval of Deptt. of Agriculture & Cooperation (Ministry of Agriculture), Dr. Ranjit Roy Choudhury, President, Delhi Society for Promotion of Rationale use of Drugs, National Institute of Immunology has been nominated as the Chairman of this Expert Committee in place of Dr. (Mrs.) S.B. Lall. Further, in consultation with the Chairman, it has been decided to hold the second meeting on 19.12.2000 at 10.00 A.M. in the Conference Hall of Central Insecticides Laboratory, Directorate of PPQ&S, NH-IV, Faridabad.

You are requested to kindly make it convenient to attend the meeting. The agenda for the second meeting of the Committee is enclosed herewith.

Yours faithfully,

S. Kulshrestha

(S. Kulshrestha)
Joint Director (Med.) &
Member-Secretary

Jt. Director (Medical Ex. Lab. etc.)

nlc m P.P.A.K

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**AGENDA FOR THE SECOND MEETING OF THE EXPERT COMMITTEE
TO REVIEW THE USE OF CHLORPYRIPHOS IN THE COUNTRY TO
BE HELD ON 19.12.2000 AT 10.00 A.M. IN THE CONFERENCE
HALL OF CIL, FARIDABAD**

Agenda Item
No. 1

Confirmation of minutes of the 1st meeting

The minutes of the 1st meeting were circulated on 23.10.2000 to all the members of the Committee. No comments have been received from any of the members. In view of this, members may like to approve the minutes of the 1st meeting.

Agenda Item
No. 2

Information/data on Chlorpyrifos

Members may kindly recall that in the 1st meeting, it was decided that the data/information on the identified parameters will be collected by the identified members and submitted to Dr. (Mrs) S. Kulshrestha, Member-Secretary. The information/data received from various members on the identified parameters is annexed as follows :

1. Chemistry - Annexure - I
2. Global registration status - Annexure - II (a)
3. Registration status in India - Annexure - III (a)
4. Global production/consumption of Chlorpyrifos Annexure-II(b)
5. Production/consumption of chlorpyrifos in India - Annexure-III (b&c)
6. Global use status of Chlorpyrifos- Annexure - II (c)
7. Uses of Chlorpyrifos in India as approved under the Insecticides Act, 1968.- Annexure - III (a)
8. Ongoing practices by the Pest Control Operators for home usage of Chlorpyrifos - Annexure - IV
9. Toxicity of Chlorpyrifos - Annexure - V (a), (b), (c)
 - (a) Acute toxicity
 - (b) Long-term and other toxicity
 - (c) Environmental toxicity
 - (d) Toxicity aspects for safe re-entry period.
10. Countries where Chlorpyrifos is banned/severely restricted.- Annexure - II (d)
11. Reason for their ban/restriction and their relevance to Indian scenario. - Annexure - II (e)
12. Alternatives available globally. - Annexure - II (f)
13. Alternatives available under the Insecticides Act for use in India. - Annexure - III (a)

Members may like to peruse and deliberate the enclosed information. It is also requested that any additional relevant information available with any of the Member of the Committee on either of these parameters may be brought to the notice of the Committee for taking appropriate decision.

Agenda Item No. 3 Format of submission of report

The report of the Chlorpyrifos review of this Committee is to be submitted to Plant Protection Advisor to the Government of India which in turn after comments of the Registration Committee will be submitted to Deptt. of Agriculture and Cooperation (Ministry of Agriculture) for taking appropriate decision. Members may like to deliberate and decide the format for preparation of report of Chlorpyrifos review in the country.

Agenda Item No. 4 Any other item with the permission of the Chair

Common Name

CHLORPYRIPHOS

Chemical Name

O,O - Diethyl O -(3,5,6 Trichloro-2
Pyridyl) Phosphorothioate

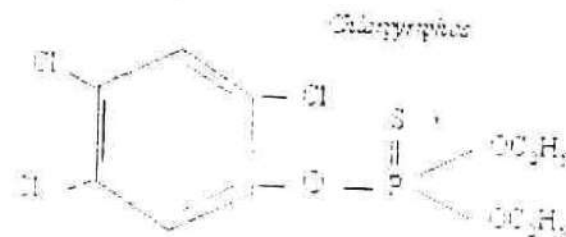
Chemical Family

Organo phosphorus compound.

Empirical Formula

 $C_8H_{11}Cl_3NO_3PS$

Structural Formula



Molecular Weight

350.6

I.S.I. No.

IS 8963 - 1978

CAS No.

2921-88-2

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Physical State Off-white to pale yellow material

Odour Mild mercaptan

Specific Gravity 1.308 ± 0.03 at 43 °C

Melting Point 41.5-43.5 °C

Solubility in Water Practically insoluble in Water

Solubility in Solvents Readily soluble in common organic solvents like acetone, benzene, ethylene dichloride, methanol etc.

Commercial Formulation (regd. in India)

- Formulation Type
- (A) Emulsifiable Concentrates
 - 1, Chlorpyrifos-20%
 - 2, Chlorpyrifos-50%
 - (B) Chlorpyrifos-1.5% DP
 - (C) Chlorpyrifos-10% G.
 - (D) Chlorpyrifos-16% +
Alphacypermethrin-1%
 - (E) Chlorpyrifos-50% +
Cypermethrin-5%

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1. Chlorpyrifos Global Registration Status

Registered in 88 Countries

1.	Algeria	45.	Korea
2.	Argentina	46.	Lebanon
3.	Austria	47.	Libya
4.	Australia	48.	Lithuania
5.	Azerbaijan	49.	Madagascar
6.	Bangladesh	50.	Mauritius
7.	Belarus	51.	Malaysia
8.	Belgium	52.	Mexico
9.	Bolivia	53.	Morocco
10.	Brazil	54.	Netherlands
11.	Bulgaria	55.	New Calidonia
12.	Cameroon	56.	New Zealand
13.	Canada	57.	Nicaragua
14.	Chile	58.	Oman
15.	China	59.	Pakistan
16.	Columbia	60.	Panama
17.	Costa Rica	61.	Paraguay
18.	Croatia	62.	Peru
19.	Cyprus	63.	Philippines
20.	Czech Republic	64.	Poland
21.	Denmark	65.	Portugal
22.	Egypt	66.	Romania
23.	El Salvador	67.	Russia
24.	Equador	68.	Saudi Arabia
25.	Ethiopia	69.	Slovenia
26.	Finland	70.	South Africa
27.	France	71.	Spain
28.	French Polynesia	72.	Sudan
29.	Germany	73.	Sweden
30.	Ghana	74.	Syria
31.	Greece	75.	Taiwan
32.	Guatemala	76.	Tanzania
33.	Honduras	77.	Thailand
34.	Indonesia	78.	Tunisia
35.	India	79.	Turkey
36.	Iran	80.	UAE
37.	Iraq	81.	UK
38.	Ireland	82.	Ukraine
39.	Israel	83.	Uruguay
40.	Italy	84.	USA
41.	Ivory Coast	85.	Uzbekistan
42.	Japan	86.	Venezuela
43.	Jordan	87.	Vietnam
44.	Kenya	88.	Zimbabwe

Gram	Pod borer	Monocrotophos 36% SL, Quinalphos 25% EC, Trichloropham 50% EC, Endosulfan 2 DP, Carbaryl 50 WP, Carbaryl 5 DP, 10 DP.
Mung	Bihar hairy-caterpillar	Phenthoate 50% EC
Sugarcane	Black bug	Formothion 25% EC, Quinalphos 25% EC, 5 G, Carbaryl 40 LV.
	Early shoot & Stalk borer	Monocrotophos 36% SL, Quinalphos 5 G, Carbonthinadane
	Pyrilla	Dichlorvos 76% EC, Fenitrothion 82.5% EC, Malathion 50% EC, 95% ULVC, Monocrotophos 36 SL, Lindane 20% EC.
Cotton	Aphid	Dimethoate 30% EC, Fenitrothion 50% EC, Formothion 25% EC, Malathion 50% EC, 95% Line Methyl Parathion 50% EC, M.P. 2% DP, Monocrotophos 36% SL, Oxydemeton methyl 25 EC, Phorate 10 G, Quinalphos 25% EC and 5% DP, Thiometon 25% EC., Endosulfan 35% EC, 4 DP, Imidacloprid 17.8 SL, Imidacloprid 70 WS, Fenvalerate 20 EC.
	Bollworms	Monocrotophos 36 SL, Phenthoate 50% EC, Quinalphos 1.5% DP, 25% EC, Methyl Parathion 50% EC, Phosalone 4 % DP. Carbaryl 50 WP, 5 DP, 10 DP, 40 LV, Acetamiprid 20 SP, Fenitrothion 50% EC, 82.5% EC, Fenthion 82.5% EC, Malathion 50% EC, 95% ULVC, Monocrotophos 36% SL, Lindane 20% EC, Phorate 10% G., Quinalphos 25% EC, Endosulfan 35 EC Carbaryl 85% WP. Acetamiprid 20 SP, Azadirachtin 0.15% EC, Triazophos 40% EC, Profenofos 50 EC, Thiodicarb 75 WP, Fenpropathrin 10 EC, Fenvalerate 20 EC.
	Grey weevil	Dimethoate 30% EC, Fenitrothion 50% EC, 82.5% EC, Malathion 95% SLVC, Monocrotophos 36% SL, Carbaryl 85% WP.
	Jassids	Dimethoate 30% EC, Fenitrothion 50% EC, 82.5% EC, Fenthion 82.5% EC, Foremothion 50% EC, Malathion 50% EC, Methyl Parathion 50% DP, Monocrotophos 36% SL, Oxydemeton Methyl 25% EC, Phorate 10 G, Phosalon 4% DP, 35% EC, Quinalphos 25% EC, 1.5% DP, Thimeton 25% EC, Endosulfan 4 DP Carbaryl 85 WP, Profenofos 50 EC, Imidacloprid 17.8 SL, Imidacloprid 70 WS, Fenvalerate 20 EC.
	Pink bollworm	Fenitrothion 50% EC, 82.5% EC, Monocrotophos 36% SL, Phenthoate 50% EC, Phosalone 35% EC, Quinalphos 1.5 DP, Quinalphos 25% EC, Carbaryl 85% WP, 50 WP.
	Whitefly	Acetamiprid 20 SP, Azadirachtin 0.15% EC, Triazophos 40% EC, Profenofos 50 EC, Quinalphos 25 EC, Imidacloprid 17.8 SL, Imidacloprid 70 WS.

Groundnut Aphid

Methyl Parathion 2% DP, Oxidemeton methyl 25% EC, Phorate 10% G, Thiometon 25% EC

Mustard Aphid

Dimethoate 30% EC, Formothion 25% EC, Malathion 50% EC, Methyl Parathion 50% EC, Monocrotophos 36% SL, Endosulfan 35 EC.

Vegetables

Brinjal Shoot & Fruit borer

Phosalone 35% EC, Trichlophon 50% EC, Endosulfan 2% DP, Lindane 6.5 WP, Carbaryl 40 LV, 50 WP, Cypermethrin 20% EC, Deltamethrin 2.8% EC, Fenvalrate 20 EC, Triazophos 40 EC, Quinalphos 25% EC.

Cabbage Diamond backmoth

Fenthion 82.5% EC, Malathion 50% EC, Phosalone 35% EC, Quinalphos 25% EC, Trichlorphos 50% EC, Carbaryl 10 DP, Fipronil 5% SC, Thiodicarb 75 WP.

Cauliflower Diamond backmoth

Diazinon 20% EC, Fenthion 82.5% EC, Malathion 50 EC, Quinalphos 25 EC, Trichlorphon 50 EC, Fenvalerate 20 EC.

Fruit trees

Apple Aphid

Lindane 20% EC, Carbaryl 50 WP.

Ber Leaf hopper

Dimethoate 30% EC

Citrus Black citrus aphid

Dimethoate 30% EC, Monocrotophos 36 SL, Oxydemeton methyl 25 EC, Phosphamidon 85 WSC

Non cropped areas

Termites Building]
Forestry]

Lindane 20% EC

2. Chlorpyrifos 1.5% DP

Uses

Crop Insect/Pest

Substitute

Paddy Stem borer

Endosulfan 4 DP

Brown plant hopper

Quinalphos 1.5 DP, Carbaryl 5 DP

Leaf folder

Carbaryl 5 DP

Grass hopper

Lindane 1.3# DP

Bengal Gram

Heliothis

Quinalphos 1.5 DP, Carbaryl 5 DP, 10 DP
Endosulfan 2% D.P.

WOOD PRESERVATION

Both raw wood (dry & damp wood) and finished wooden products/articles are prone to the damage by termites and wood boring insects. There is a need to have an effective and comparatively and safer wood preservative both for use on wooden articles meant for domestic use and exportable wooden items, wherein many of the importing countries insist on being free from pest infestation.

Though in 1998 Lindane 20 % EC has been approved by the Registration Committee for wood protection against termite attack, based on the evaluation conducted at the National Institute of Technology, New Delhi; Forest Research Institute, Dehradun and National Chemical Laboratory, Pune. Its present usage is nil to negligible.

Chlorpyrifos 2 % w/w solution as wood preservative

This formulation has been recently evaluated at the Indian Institute of Wood, Science & Technology, Bangalore; Indian Plywood Industries Research & Training Institute, Bangalore; National Chemical Laboratory, Pune; and Forest Research Institute, Dehradun, for its effectiveness in containing termite damage and damage due to wood boring insects in our country. Highly susceptible wood species viz., Rubber, Poplar, Silver Oak, Mango wood etc... were subjected to evaluation with this insecticide. The treatment by way of dipping, spraying, brushing, pressure impregnation etc.. revealed that this formulation is effective against both termites and wood boring insects.

Safety evaluation (in experimental animals)

Acute toxicity studies (Oral, Dermal, Primary Skin Irritation & Mucus Membrane Irritation), Toxicity to Birds, Fish & Honey Bees are reported to have margin of safety to non-target species.

Health Monitoring Studies (on Human Volunteers)

These studies have been conducted as per the Protocol approved by the Registration Committee and completed during August 2000. Human volunteers (Inmates of houses) included male & female adults and children.

Based on the data obtained it is concluded that spraying the above formulation did not cause health hazard to human volunteers, operators and inhabitants as judged by the parameters studied.

Summary

The studies conducted with Chlorpyrifos 2 % w/w solution reveals that it is effective to curb damage by termite & wood boring insects in variety of woods. It is also comparatively safer to non-target experimental animal and human beings.

An application for Registration of above formulation (from a member of IPCA) is under scrutiny in the Registration Secretariat.

It is relevant to mention that several Chlorpyrifos formulations are already approved and used for wood preservation/treatment in several countries.

The above factual position requires to be kept into consideration during the forthcoming review meeting, for arriving at appropriate conclusion and make suitable recommendations on Chlorpyrifos use in our country.

**ESTIMATING RESIDUES
in food - 1999**

Annex V

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Joint FAO / WHO Meeting on
Pesticide Residues

EVALUATIONS

1999

PART II - Toxicological

IPCS

International Programme on Chemical Safety

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cholinesterase activity was seen during a short period. In the third study, erythrocyte cholinesterase activity was not affected by treatment, but plasma cholinesterase activity was reduced by 50–80% in spraymen using a suspension formulation. The activity had generally returned to pre-exposure levels within 2 months of cessation of use. Four spraymen using an emulsion formulation did not show reduced plasma cholinesterase activity during the exposure period (Kenaga, 1967; Eliason et al., 1969).

3.4 Studies of morbidity

In a study in which the sample size was small and the statistical power was limited, comparisons were made between 175 employees potentially exposed to chlorpyrifos at a manufacturing plant where they had held jobs between 1 January 1977 and 31 July 1985 and 335 unexposed controls matched on age (within 5 years), date of hire (within 5 years), sex, race, and pay status. The source of information for the observations (self, nurse, company physician, private physician, laboratory) was recorded, as were use of tobacco, alcohol, and cholinergic drugs. Exposure was grouped into high, moderate, and low on the basis of industrial hygiene surveys and consultation with veteran manufacturing personnel. The plasma cholinesterase activities of the potentially exposed employees before exposure were available, and follow-up was conducted at roughly monthly intervals. The mean inhibition of plasma cholinesterase activity was $19 \pm 2.9\%$ in the group with low exposure, $32 \pm 2.8\%$ in that with moderate exposure, and $32 \pm 5.3\%$ in that with high exposure. No cases of peripheral neuropathy were recorded in the study group. Inhibition of plasma cholinesterase activity was observed but was not associated with illness. The exposed groups reported symptoms of dizziness, malaise, and fatigue more frequently than the unexposed group, but the analysis did not indicate any correlation with increasing exposure (Brenner et al., 1989).

In a follow-up to this study (Burns et al., 1998), the data were updated to include the period 1987–94, and additional medical disorders were considered. Data on self-reported paraesthesia were collected from 1982 to 1994. The prevalence of peripheral neuropathy was not significantly increased in the group of workers exposed to chlorpyrifos.

Comments

After oral administration to rats, radiolabelled chlorpyrifos was rapidly and extensively absorbed (up to about 90% of the dose) and eliminated, predominantly in the urine (68–93%) and faeces (6–15% of the dose), within about 72 h of administration. The urinary metabolites included the glucuronide (about 80%) and sulfate (about 5%) conjugates of chlorpyrifos, and 3,5,6-trichloro-2-pyridyl phosphate (TCP; about 12%). The tissue concentrations of residues of [¹⁴C]chlorpyrifos were very low (generally < 1 ppm) within 72 h of dosing. The longest half-time of residues in rats was 62 h in fat, and low levels were also detected in the fat of several other species and in the milk of goats.

In humans who were poisoned with chlorpyrifos formulations, diethylphosphorus metabolites were excreted in the urine by first-order kinetics, with an average elimination half-time of 6.1 ± 2.2 h in the fast phase and of 80 ± 26 h in the slow phase. In volunteers, the time to maximal concentration of 3,5,6-TCP in the blood was 0.5 h after oral dosing and 22 h after dermal treatment, but the elimination half-time by both routes was 27 h, and the percentage of the administered dose recovered from the urine was 70% after oral dosing and 1.3% after dermal administration.

Chlorpyrifos is rapidly metabolized by mixed-function oxidases to the highly reactive chlorpyrifos oxon by oxidative desulfuration. The oxon can be deactivated by hydrolysis to diethylphosphate and 3,5,6-trichloropyridinol, while a minor reaction pathway is hydrolysis to monoethyl 3,5,6-trichloro-2-pyridinyl phosphorothioate.

The lowest oral LD₅₀ value was 96 mg/kg bw (range, 96–175 mg/kg bw) in rats and 100 mg/kg bw (range, 100–150 mg/kg bw) in mice. Female rats were generally more sensitive to the acute effects of chlorpyrifos than males. The signs of acute intoxication with chlorpyrifos were consistent with cholinesterase inhibition. The acute dermal LD₅₀ of chlorpyrifos was > 2000 mg/kg bw in rats and > 1200 mg/kg bw in rabbits.

WHO (1999) has classified chlorpyrifos as 'moderately hazardous'.

Chlorpyrifos was irritating to the eye and skin of rabbits, but it did not sensitize the skin of guinea-pigs in Magnusson-Kligman maximization or Buehler tests.

In short-term studies, the NOAEL for inhibition of erythrocyte cholinesterase activity was 0.03 mg/kg bw per day in dogs and 0.1 mg/kg bw per day in rats. The NOAEL for inhibition of brain cholinesterase activity was 1 mg/kg bw per day in dogs and rats. The signs of toxicity were largely limited to cholinergic signs and decreased body weights and/or food consumption. The NOAEL for these effects in short-term studies was 1 mg/kg bw per day in rats, and the NOAEL for clinical signs was 3 mg/kg bw per day in dogs. In mice, ocular effects and histopathological alterations (including adrenal lipogenic pigmentation and ocular keratitis) were observed (NOAEL, 50 ppm; equal to 7 mg/kg bw per day). In rats, the NOAEL for increased fatty vacuolation of the adrenal zonal fasciculata and changes in haematological and clinical chemical parameters was 5 mg/kg bw per day. When rats received chlorpyrifos dermally for 21 days, the NOAEL for inhibition of cholinesterase activity in erythrocytes and brain was 5 mg/kg bw per day.

In long-term studies, inhibition of cholinesterase activity was again the main toxicological finding in all species. In rats, the NOAEL was 0.1 mg/kg bw per day for inhibition of erythrocyte acetylcholinesterase activity and 1 mg/kg bw per day for inhibition of brain acetylcholinesterase activity, but clinical signs were not seen at doses up to 10 mg/kg bw per day, and the NOAEL for reduction in body weight was 1 mg/kg bw per day. In mice, erythrocyte and brain acetylcholinesterase activities were inhibited at 50 ppm, equal to 6.1 mg/kg bw per day, and the NOAEL was 5 ppm, equal to 0.7 mg/kg bw per day. Cholinergic signs and reductions in body weight were reported only at the highest dietary concentration of 250 ppm (equal to 32 mg/kg bw per day). Other treatment-related findings included effects on the liver in mice, with a NOAEL of 50 ppm (equal to 6.6 mg/kg bw per day), and increased adrenal weight in rats with a NOAEL of 1 mg/kg bw per day. There was no treatment-related increase in the incidence of neoplastic lesions in any of the long-term studies. The Meeting concluded that chlorpyrifos is unlikely to pose a carcinogenic risk to humans.

Chlorpyrifos was not genotoxic in an adequate range of studies *in vitro* and *in vivo*. The Meeting concluded that chlorpyrifos is not genotoxic.

In multigeneration studies of reproductive toxicity in rats, the treatment-related effects of chlorpyrifos were limited to inhibition of cholinesterase activity, consistent with that seen in other short- and long-term studies, and fetotoxicity characterized by reduced pup viability, body weights and survival. No significant, treatment-related clinical signs were reported. The NOAEL for inhibition of maternal acetylcholinesterase activity was 0.1 mg/kg bw per day for erythrocytes and 1 mg/kg bw per day for brain. The NOAEL for developmental toxicity was 1 mg/kg bw per day. No effects on reproductive parameters were observed at the highest dose tested, 5 mg/kg bw per day.

In studies of developmental toxicity in mice, rats, and rabbits, the maternal effects included inhibition of erythrocyte and/or brain acetylcholinesterase activity and cholinergic signs (lowest NOAEL, 1 mg/kg bw per day in rats and mice) and reductions in body weight and food consumption (lowest NOAEL, 2.5 mg/kg bw per day in rats). The observed fetal toxicity (lowest NOAEL, 2.5 mg/kg bw per day in rats) and developmental toxicity (NOAEL, 1 mg/kg bw per day in rats) were consistent with treatment-related maternal toxicity; there was no evidence of treatment-related malformations in any of the studies. There was no effect on cognitive function (learning, memory, and habituation) in pups exposed to chlorpyrifos *in utero* and for a period *post partum* at doses up to and including the highest dose of 5 mg/kg bw per day, while inhibition of cholinesterase activity, decreased brain weight, and delayed development were seen at lower doses, consistent with findings in other studies.

In studies of delayed neurotoxicity, chlorpyrifos was given to chickens as either single or repeated doses. Significant inhibition of both cholinesterase and neuropathy target esterase activity was observed, and mild delayed neuropathy was seen in a number of studies; aggressive antidotal therapy was always necessary to allow at least some of the treated birds to survive. Despite the marked cholinergic toxicity of chlorpyrifos, there was no evidence that it caused delayed neurotoxicity, and there was no increase in the incidence of histopathological lesions in the nerve tissues of birds treated at doses up to 10 mg/kg bw per day for up to 91 days. In a number of studies in rats given single doses of up to 100 mg/kg bw, repeated doses of up to 10 mg/kg bw per day for 4 weeks, or repeated doses of up to 15 mg/kg bw per day for 13 weeks, there were no treatment-related neurological lesions or effects on cognition and no inhibition of neuropathy target esterase activity, although significant inhibition of erythrocyte, brain, and peripheral tissue

cholinesterase activity was seen at some doses. In a study that included a functional observational battery of tests, clinical signs of intoxication were observed after a single dose only when brain acetylcholinesterase activity was inhibited by more than 60% or when whole-blood cholinesterase activity was inhibited by more than 80%.

When chlorpyrifos was applied as a single dose of up to 5 mg/kg bw to the skin of volunteers for 12 h, erythrocyte cholinesterase activity was not significantly inhibited. Plasma cholinesterase activity was inhibited after 20 12-h dermal exposures to 5 mg/kg bw per day over 4 weeks or after three daily 12-h exposures to 25 mg/kg bw per day on consecutive days, but erythrocyte cholinesterase activity was not inhibited under any treatment regimen.

A single oral dose of up to 1 mg/kg bw or repeated doses of up to 0.1 mg/kg bw per day for 9 days did not significantly inhibit erythrocyte acetylcholinesterase activity in volunteers. No clinical signs were observed in these studies. Inhibition of erythrocyte acetylcholinesterase activity was observed in a single female volunteer (of a group of six men and six women) given a single oral dose of 2 mg/kg bw.

In a case of human poisoning with chlorpyrifos at an estimated dose of 300-400 mg/kg bw, significant inhibition of neuropathy target esterase in lymphocytes and of plasma and erythrocyte acetylcholinesterase activity was reported, with severe cholinergic signs which required aggressive, extensive antidotal therapy and artificial ventilation. Mild distal axonopathy consistent with organophosphate-induced delayed polyneuropathy was reported some weeks after the poisoning incident.

The ADI of 0-0.01 mg/kg bw established by the 1982 Meeting was based on a NOAEL of 0.1 mg/kg bw per day for inhibition of erythrocyte acetylcholinesterase activity in humans. The present Meeting affirmed this ADI on the basis of the NOAEL of 1 mg/kg bw per day for inhibition of brain acetylcholinesterase activity in studies in mice, rats, and dogs, using a 100-fold safety factor, and on the basis of the NOAEL of 0.1 mg/kg bw per day for inhibition of erythrocyte acetylcholinesterase activity in the study of human subjects exposed for 9 days, using a 10-fold safety factor.

The Meeting allocated an acute reference dose of 0.1 mg/kg bw on the basis of the NOAEL of 1 mg/kg bw for inhibition of erythrocyte acetylcholinesterase activity in a study in which volunteers received a single oral dose of chlorpyrifos, with a safety factor of 10.

Toxicological evaluation

Levels that cause no toxic effect

- Mouse: 5 ppm, equal to 0.7 mg/kg bw per day (toxicity in a 79-week study of toxicity and carcinogenicity)
1 mg/kg bw per day (maternal toxicity in a study of developmental toxicity)
10 mg/kg bw/day (fetal toxicity in a study of developmental toxicity)
- Rat: 1 mg kg bw per day (toxicity in 2-year studies of toxicity and carcinogenicity)
1 mg kg bw per day (developmental and parental toxicity in a two-generation study of reproductive toxicity)
1 mg kg bw per day (maternal and developmental toxicity in a study of developmental toxicity)
2.5 mg kg bw per day (fetal toxicity in a study of developmental toxicity)
- Rabbit: 81 mg kg bw per day (maternal and fetal toxicity in a study of developmental toxicity)
- Dog: 1 mg kg bw per day (toxicity in a 2-year study of toxicity)
- Human: 0.1 mg/kg bw per day (no inhibition of erythrocyte cholinesterase activity at highest dose tested in men dosed orally for 9 days)
1 mg/kg bw (inhibition of erythrocyte cholinesterase activity in adult volunteers after a single oral dose)

Estimate of acceptable daily intake for humans

0-0.01 mg/kg bw

Estimate of acute reference dose

0.1 mg/kg bw

Studies that would provide information useful for continued evaluation of the compound

Further observations in humans

Toxicological end-points relevant for setting guidance values for dietary and non-dietary exposure to chlorpyrifos

Absorption, distribution, excretion, and metabolism in mammals

Rate and extent of oral absorption	Up to 90% in rats within 72 h; about 70% in humans within 96 h
Dermal absorption	Less than 2% in humans within 180 h; not determined in animals
Distribution	Initially widely distributed; highest residues in liver, kidneys and fat at 72 h in rats
Potential for accumulation	Elimination half-times of < 24 h and low tissue residues after 72 h in rats. No evidence of potential for accumulation
Rate and extent of excretion	> 95% within 72 h in rats, mainly in urine (68-93%) and faeces (6-15%)
Metabolism in animals	Rapidly metabolized by mixed-function oxidases to chlorpyrifos oxon via oxidative desulfuration and an electrophilic phosphooxathiiran intermediate. Degradation by conversion directly to 3,5,6-trichloro-2-pyridyl phosphate and diethyl thiophosphate. The oxon is hydrolysed to diethyl phosphate and 3,5,6-trichloropyridinol, while a minor reaction pathway is by hydrolysis to monoethyl-3,5,6-trichloro-2-pyridinol phosphorothioate.
Toxicologically significant compounds (animals, plants and environment)	Parent compound and oxon

Acute toxicity

Rat., LD ₅₀ , oral	96 mg kg bw
Rat LD ₅₀ , dermal	> 2000 mg kg bw
Rat, LC ₅₀ , inhalation	> 36 mg m ⁻³ (4 h, vapour, nose-only exposure) > 60 mg m ⁻³ (4 h, nebulized particles < 5 µm, whole-body exposure)
Rabbit, dermal irritation	Slightly irritating
Rabbit, ocular irritation	Slightly irritating
Guinea-pig, dermal sensitization	Not sensitizing

Short-term toxicity

Target/critical effect	Inhibition of brain cholinesterase activity
Lowest critical oral NOAEL	1 mg kg bw per day, dog, 2 years 1 mg kg bw per day, rat, 13 weeks
Lowest relevant dermal NOAEL	5 mg kg bw per day, rat, 21 days
Lowest relevant inhalation NOAEL	20.6 ppb (296 µg/m ³), rat, 13 weeks

Long-term toxicity and carcinogenicity

Target/critical effect	Inhibition of brain cholinesterase activity
Lowest relevant NOAEL	2 years, rat: 1 mg kg bw per day 78 weeks, mouse: 0.7 mg kg bw per day
Carcinogenicity	Not carcinogenic in rats or mice

<i>Genotoxicity</i>	Not genotoxic
<i>Reproductive toxicity</i>	Neonatal toxicity (reduced pup body weight and survival) Two-generation, rat; 1 mg/kg bw per day Fetal and perinatal toxicity at maternally toxic doses (including an increase in delayed ossification, reduced crown-rump length, reduced pup weight, increased postimplantation loss, delayed sexual maturity) Rats; 1 mg/kg bw per day
Reproductive target/critical effect Lowest relevant reproductive NOAEL Developmental target/critical effect	
Lowest relevant developmental NOAEL	
<i>Neurotoxicity/Delayed neurotoxicity</i>	Reversible neurotoxicity consistent with cholinesterase inhibition. No evidence of delayed neurotoxicity or histopathological changes in nerves of hens (10 mg/kg bw per day) and rats (15 mg/kg bw per day) for up to 13 weeks. At high acute doses (up to 150 mg/kg bw), significant inhibition of neuropathy target esterase and mild delayed neuropathy in hens, but at this dose, extensive and aggressive antidote treatment were required for birds' survival.
<i>Other toxicological studies</i>	No effect on cognitive function in rat pups in a study of developmental toxicity at doses up to 5 mg/kg bw per day
<i>Medical data</i>	No inhibition of erythrocyte acetylcholinesterase activity in volunteers after repeated oral doses of up to 0.1 mg/kg bw per day (for 9 days), single oral doses of up to 1 mg/kg bw, or a single dermal doses of 5 mg/kg bw. Poisoning case presented with severe cholinergic effects, with evidence of delayed polyneuropathy and/or distal axonopathy at a dose that required antidotal treatment and artificial ventilation.

Summary	Value	Study	Safety factor
ADI	0-0.01 mg/kg bw	Rat, 2-year dietary Rat, reproduction Mouse, developmental toxicity Dog, 2-year dietary Human, 9-day oral	100 10
Acute reference dose	0.1 mg/kg bw	Human, single dose	10

References

Aiuto, L.A., Pavliakis, S.G. & Boxer, R.A. (1993a) Life-threatening organophosphate-induced delayed polyneuropathy in a child after accidental chlorpyrifos ingestion. *J. Pediatr.*, **122**, 658-660.

Aiuto, L.A., Pavliakis, S.G. & Boxer, R.A. (1993b) Organophosphate-induced delayed polyneuropathy (comment). *J. Pediatr.*, **123**, 837.

Aldridge, W.N. (1953) Serum esterases I. *J. Biochem.*, **53**, 110-117.

Anderson, B.T., Walker, S.A. & Punier, M.J. (1995) Chlorpyrifos tech: Acute inhalational toxicity study in rats. Unpublished report No. 10425 from Inveresk Research International, Tranent, Scotland. Submitted to WHO by Luxembourg Industries, Tel Aviv, Israel.

Bakke, J.E., Feil, V.J. & Price, C.E. (1976) Rat urinary metabolites from O,O-diethyl-O(3,5,6-trichloro-2-pyridyl) phosphorothioate. *J. Environ. Sci. Health Bull.*, **3**, 225-230.

Barna-Lloyd, T. & Szabo, J.R. (1985) Sodium 3,5,6-trichloro-2-pyridinol: 3-month rat dietary toxicity study. Unpublished report No. TexasT-K-065999-099 from Dow Chemical Co., USA. Submitted to WHO by Dow AgroSciences, Indianapolis, IN, USA.

Abstracts from peer-reviewed journal articles on the health effects of Chlorpyrifos

From medline search, 2/1/99

01. TITLE: Potential chlorpyrifos exposure to residents following standard crack and crevice treatment.

SOURCE: Environ Health Perspect 1998 Nov;106(11):725-31

ABSTRACT: Multipathway exposures were evaluated for residents of houses over a 10-day period following a crack and crevice application of a chlorpyrifos-based formulation. Three multiroom houses with two adults each were treated. Air concentration, total deposition, and dislodgeable residues on horizontal surfaces were measured to assess potential respiratory, oral, and dermal exposures, respectively, in treated and untreated high activity rooms. In addition, urine samples collected from the adults were analyzed for the primary metabolite of chlorpyrifos, 3,5,6-trichloropyridinol, to determine absorbed dose. The maximum chlorpyrifos air concentration observed was 2.3 microgram/m³, with air concentrations generally decreasing to levels ranging from 0.1 to 0.3 microgram/m³ within 10 days. Carpet dislodgeable residues, used to evaluate the amount of residues potentially transferred upon contact, were less than the analytical method limit of quantitation (1.6 microgram/m²). Hard plastic balls placed in the homes on the day before application contained no detectable dislodgeable residues (<6.5 microgram/m²). Ten-day cumulative nontarget residues deposited on surfaces, as determined by deposition pads, were less than 2.3 microgram/100 cm². Deposition samples from all living area floors collected 2 hr after application contained less than 9.9 microgram/100 cm². **Therefore, contact with household surfaces and subsequent hand-to-mouth activity are not expected to significantly contribute to overall exposure.** Estimated exposures to children, based on the passive dosimetry measurements, ranged from 0.26 to 2.1% of the no observed effect level for plasma cholinesterase depression. In addition, potential exposures to the adult residents, as indicated by the urinary 3,5,6-TCP biomonitoring, did not increase as a result of the application.

02. TITLE: Human exposure and risk from indoor use of chlorpyrifos.

SOURCE: Environ Health Perspect 1998 Jun;106(6):303-6

ABSTRACT: The toxicity, exposure, and risk from chlorpyrifos are briefly discussed in juxtaposition with two recent articles in Environmental Health Perspectives concerning potential exposures to children. **In studies conducted according to EPA guidelines, chlorpyrifos has been shown not to be mutagenic, carcinogenic, or teratogenic, nor does it adversely affect reproduction.** Chlorpyrifos toxicity does not occur in the absence of significant cholinesterase inhibition. If exposures are less than those that cause significant cholinesterase depression, then no signs or symptoms related to chlorpyrifos

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exposure occur. **The weight of empirical evidence indicates that the risk of adults or children experiencing an adverse health effect from exposure to chlorpyrifos through both nondietary and dietary sources is negligible.** Both the research supporting the registration of these products and their long history of widespread use suggest that unless these products are seriously misused, their margins of safety are wide enough to protect everyone with the potential to be exposed.

A weight-of-evidence review of the entire scientific knowledge base relating to chlorpyrifos products supports these conclusions.

03. TITLE: Exposures from indoor spraying of chlorpyrifos pose greater health risks to children than currently estimated.

SOURCE: Environ Health Perspect 1998 Jun;106(6):299-301

ABSTRACT: Recent findings of indoor exposure studies of chlorpyrifos indicate that young children are at higher risks to the semivolatile pesticide than had been previously estimated [Gurunathan et al., Environ Health Perspect 106:9-16 (1998)]. The study showed that after a **single broadcast use of the pesticide by certified applicators in apartment rooms, chlorpyrifos continued to accumulate on children's toys and hard surfaces 2 weeks after spraying.** Based on the findings of this and other research studies, the estimated chlorpyrifos exposure levels from indoor spraying for children are approximately 21-119 times above the current recommended reference dose of 3 microg/kg/day from all sources. A joint agreement reached between the U.S. Environmental Protection Agency and the registrants of chlorpyrifos-based products will phase out a number of indoor uses of the pesticide, including broadcast spraying and direct uses on pets. While crack and crevice treatment of insects (such as cockroaches and termites) by chlorpyrifos will still continue, it appears prudent to explore other insect control options, including the use of baits, traps, and insect sterilants and growth regulators. To ensure global protection, adequate dissemination of appropriate safety and regulatory information to developing regions of the world is critical, where importation and local production of chlorpyrifos-based products for indoor uses may be significant.

04. TITLE: Accumulation of chlorpyrifos on residential surfaces and toys accessible to children [In Process Citation]

SOURCE: Environ Health Perspect 1998 Apr;106 Suppl 2:9-16

ABSTRACT: Quantitative examination of major pathways and routes of exposure to pesticides is essential for determining human risk. The current study was conducted in two apartments and examines the accumulation of the pesticide chlorpyrifos in children's toys after the time suggested for reentry after application. **It has been established for the first time that a semivolatile pesticide will accumulate on and in toys and other sorbant surfaces in a home via a two-phase physical process that continues for at least 2 weeks postapplication.** A summation of the above for a 3-6-year-old child yielded an estimated nondietary total dose of 208 microg/kg/day. Potential exposure from the inhalation pathway was negligible, while dermal and nondietary oral doses

06.TITLE: Penetration of household insecticides through different types of textile fabrics.

SOURCE: Chemosphere 1998 Mar;36(7):1543-52

ABSTRACT: **Six different types of fabrics were compared for their ability to protect against human exposure to three different commercial household aerosol insecticides.** Fabrics used in this investigation were, 100% cotton, cotton-polyester thermal underwear, cotton-polyester blend (twill), 100% acrylic, 100% wool and artificial silk (rayon). The household insecticides were, Black Flag (Ant and Roach Killer), Raid (Ant and Roach Killer) and Hot Shot (Wasp and Hornet Killer) containing propoxur, permethrin/pyrethrins and **chlorpyrifos/allevethrins as their active ingredients respectively.** A fluorescent tracer, 4-methyl-7-diethyl amino coumarin was mixed with the aerosol (or equivalent aliquot) and sprayed onto cloth squares fitted on Whatman paper patches. The percentage of penetration through the cloth was quantified by the intensity of the fluorescence spectrum of each patch extract and the amount of the tracer recovered was calculated. The extract was concentrated to 1/10th of the volume to measure the content of each of the insecticides by supercritical fluid chromatography (SFC) using electron capture (ECD) and diode array detectors. Scanning electron microscope (SEM) images of the fabrics showed the geometry of the yarn. The results obtained from the fluorescence spectra, SFC and SEM showed that cotton-polyester (twill), cotton, wool and cotton thermal underwear were the least penetrable materials for the aerosols. On the other hand, acrylic and artificial silk (rayon) were the most penetrable cloth types.

07.TITLE: Potential health risks from indoor exposure to chlorpyrifos (O,O- diethyl O-[3,5,6-trichloro-2-pyridyl] phosphorothioate).

SOURCE: Rev Environ Health 1997 Apr-Jun;12(2):91-7

ABSTRACT: **A four-season, indoor air quality survey was conducted in Southern Louisiana to determine the indoor air levels of the pesticide chlorpyrifos.** Gas chromatographic analysis of 213 air samples collected from 53 houses revealed levels of chlorpyrifos ranging from non-detected to 2.13 micrograms/m³. Using the Florida-Pinella exposure guideline (24-hr exposure to chlorpyrifos at 0.48 microgram/m³), it was noted that 14% of the samples exceeded this guideline. **The exposure of occupants to the indoor air concentrations of the pesticide, however, were below either the irritation or the odor thresholds, and effects on acute and chronic health responses remains uncertain.**

08.TITLE: Pesticide exposures to children from California's Central Valley: results of a pilot study.

SOURCE: J Expo Anal Environ Epidemiol 1997 Apr-Jun;7(2):217-34

ABSTRACT: **In response to concerns about pesticide use and evidence that contaminants may accumulate in house dust, the California Department of Health Services (DHS) conducted a pilot study of pesticide contamination in rural**

children's home environments. House dust samples for pesticide analysis were collected from eleven homes, five of which had at least one farmworker (FW) resident. Handwipe samples were collected from one child at each residence (ages 1-3 years). Ten of 33 pesticides tested in house dust were detected. Excluding non-detects, concentrations for diazinon ranged from 0.7-169 ppm in four FW homes and 0.2-2.5 ppm in three non-farmworker (NFW) homes (overall median = 1 ppm), suggesting a difference between FW and NFW homes. Chlorpyrifos ranged from 0.2-33 ppm in three FW homes and < 1 ppm in two NFW homes (overall median < 0.5 ppm). All other pesticides were detected at < 2 ppm at four or fewer homes. The sources of these compounds could not be determined. Co-located samples were considerably different in concentration and loading, indicating intra-household variation. Of nine compounds tested, diazinon and chlorpyrifos were found on the hands of two or three FW children (20-220 ng/hand). Dust ingestion scenarios show child exposures could exceed the United States Environmental Protection Agency Office of Pesticide Program diazinon chronic reference dose (9×10^{-5} mg/kg/day). The results suggested that pesticide residues are present in the home environment of some California children and are likely to contribute to exposures. Additional research is feasible and needed to assess the magnitude and distribution of these risks.

09.TITLE: Improper use of an insecticide at a kindergarten.

AUTHORS: Fischer AB; Eikmann T

AUTHOR AFFILIATION: Institute of Hygiene and Environmental Medicine, Justus-Liebig- University, Giessen, Germany.

SOURCE: Toxicol Lett 1996 Nov;88(1-3):359-64

CITATION IDS: PMID: 8920761 UI: 97079029

ABSTRACT: In a German kindergarten cockroaches were destroyed by a commercial firm. A preparation containing pyrethrum and its synergist piperonyl butoxide and the organic phosphorus pesticide chlorpyrifos was sprayed. While cleaning the rooms, the staff complained of health effects. Thereupon the kindergarten was closed until further notice, samples were taken by the health authorities for chemical analysis, and an environmental medical evaluation was initiated. The analytical results are presented. The toxicological significance of the employed insecticides, their environmental persistence, and the problems associated with pest control in such institutions are discussed and recommendations given.

10.TITLE: Dietary exposures to selected metals and pesticides.

SOURCE: Environ Health Perspect 1996 Feb;104(2):202-9

ABSTRACT: Average daily dietary exposures to 11 contaminants were estimated for approximately 120,000 U.S. adults by combining data on annual diet, as measured by a

food frequency questionnaire, with contaminant residue data for table-ready foods that were collected as part of the annual U.S. Food and Drug Administration Total Diet Study. **The contaminants included in the analysis were** four heavy metals (arsenic, cadmium, lead, mercury), **three organophosphate pesticides (chlorpyrifos, diazinon, malathion),** and four organochlorine pesticides (dieldrin, p,p'-DDE, lindane, heptachlor epoxide). Dietary exposures to these contaminants were highly variable among individuals, spanning two to three orders of magnitude. Intraindividual exposures to the metals, organophosphates, and organochlorines were estimated to be strongly correlated; Pearson's correlation coefficients ranged from 0.28 for lindane:dieldrin to 0.84 for lead:mercury. For some of the compounds (e.g., arsenic and dieldrin), a substantial fraction of the population was estimated to have dietary intakes in excess of health-based standards established by the EPA. Before use for risk assessment or epidemiologic purposes, however, the validity of the exposure estimates must be evaluated by comparison with biological indicators of chronic exposure. **Because of their low detection rate in table-ready foods, the estimated distributions of exposures for dieldrin, p,p'-DDE, heptachlor epoxide, lindane, diazinon, and chlorpyrifos were found to be sensitive to assumed values for nondetect samples.** Reliable estimates of the population distribution of dietary exposures to most other contaminants cannot be made currently, due to their low rate of detection in table-ready foods. Monitoring programs that use more sensitive study designs and population-based assessments for other subpopulations should be a priority for future research.

11. TITLE: Chlorpyrifos (Dursban)-associated birth defects: report of four cases.
 SOURCE: Arch Environ Health 1996 Jan-Feb;51(1):5-8

ABSTRACT: Extensive and unusual patterns of birth defects noted in four children included defects of the brain, eyes, ears, palate, teeth, heart, feet, nipples, and genitalia. Brain defects were present in the ventricles, corpus callosum, choroid plexus, and septum pellucidum, and genital defects included the testes (undescended), microphallus, and labia fused. All children had growth retardation, and three had hypotonia and profound mental retardation. **The children were exposed in utero to chlorpyrifos (Dursban).** Published literature and unpublished documents by the U.S. Environmental Protection Agency contain reports that identify similarities in defects found in test animals and in children exposed to Dursban. **A pattern of defects found in the four children in this study may represent a heretofore unrecognized syndrome that should be considered when Dursban-exposed women have children with birth defects.**

12. TITLE: Pesticides in household dust and soil: exposure pathways for children of agricultural families.
 SOURCE: Environ Health Perspect 1995 Dec;103(12):1126-34

ABSTRACT: Child of agriculture families are likely to be exposed to agricultural chemicals, even if they are not involved in farm activities. This study was designed to determine whether such children are exposed to higher levels of pesticides than children whose parents are not involved in agriculture and whose homes are not close to farms.

Household dust and soil samples were collected in children's play areas from 59 residences in eastern Washington State (26 farming, 22 farmworker, and 11 nonfarming families). The majority of the farm families lived within 200 feet of an operating apple or pear orchard, whereas all reference homes were located at least a quarter of a mile from an orchard. Four organophosphorous (OP) insecticides commonly used on tree fruit were targeted for analysis: azinphosmethyl, **chlorpyrifos**, parathion, and phosmet. Samples were extracted and analyzed by gas chromatography/mass selective detection. Pesticide concentrations in household dust were significantly higher than in soil for all groups. OP levels for farmer/farm-worker families ranged from nondetectable to 930 ng/g in soil (0.93 ppm) and from nondetectable to 17,000 ng/g in dust (17 ppm); all four OP compounds were found in 62% of household dust samples, and two-thirds of the farm homes contained at least one OP above 1000 ng/g. Residues were found less frequently in reference homes and all levels were below 1000 ng/g. Household dust concentrations for all four target compounds were significantly lower in reference homes when compared to farmer/farmworker homes (Mann Whitney, U test; $p < 0.05$). These results demonstrate that children of agricultural families have a higher potential for exposure to OP pesticides than children of nonfarm families in this region. Measurable residues of a toxicity, I compound registered exclusively for agricultural use, azinphosmethyl were found in household dust samples from all study homes, suggesting that low level exposure to such chemicals occurs throughout the region. **Children's total and cumulative exposure to this pesticide class from household dust, soil, and other sources warrants further investigation.**

13. TITLE: Exposure to pesticides in ambient air.

SOURCE: Aust J Public Health 1995 Aug;19(4):357-62

ABSTRACT: Ambient air was monitored for pesticides at four sites in Coffs Harbour, a coastal town (population about 50,000) surrounded by banana plantations. Air was sampled continuously for five consecutive months during the peak agricultural spraying period using vacuum pumps set to sample one litre per minute through ORBO-42 absorption tubes. Six pesticides were detected: three organochlorines and three organophosphates. The most commonly detected pesticide (14 per cent of all samples) was chlorpyrifos (maximum detected level 208.0 ng/m³, mean 3.6 ng/m³). Heptachlor was detected in 7.1 per cent of all samples (maximum detected level 133 ng/m³, mean 2.7 ng/m³). Other pesticides were only rarely detected. The only pesticide applied by air in the district (propiconazole) was not detected. If international health guidelines are used as a yardstick, these levels of exposure appear unlikely to present an appreciable health risk. Chlorpyrifos detection was associated with low wind speed ($P = 0.012$) and high temperature ($P = 0.015$), and detection at one site was associated with detection at another ($P < 0.001$). Chlorpyrifos detection was also associated with domestic applications within the town area as reported by pesticide applicators ($P = 0.045$). **Peak agricultural use of chlorpyrifos did not coincide with peak detection periods.** None of the detected organochlorines is registered for agricultural use, although at the time, heptachlor was permitted for use as a domestic termiticide. Even in a semirural town with nearby widespread use of agricultural chemicals, community exposures to pesticides in ambient air may largely relate to their nonagricultural use.

14.TITLE: Chlorpyrifos: hazard assessment based on a review of the effects of short-term and long-term exposure in animals and humans.

SOURCE: Food Chem Toxicol 1995 Feb;33(2):165-72

ABSTRACT: Analyses of potential dietary exposure to chlorpyrifos residues were conducted by the Department of Pesticide Regulation (DPR). Potential acute dietary ingestion of chlorpyrifos for all labelled uses was based on the 95th percentile of user-day exposures. Margins of safety (MOSs) for potential acute dietary exposure to chlorpyrifos residues were based on a no-observed-effect level (NOEL) for cholinergic signs in a human study, and ranged from 52 to 205 for all population subgroups. MOSs for potential chronic dietary exposure to chlorpyrifos residues were based on a NOEL for inhibition of brain cholinesterase activity in rats and dogs, and ranged from 2198 to 8065 for all population subgroups. The limitations on toxicity, consumption and residue data are discussed, with the assumptions necessitated by those limitations.

15.TITLE: Assessment of the neurotoxic potential of chlorpyrifos relative to other organophosphorus compounds: a critical review of the literature.

SOURCE: J Toxicol Environ Health 1995 Feb;44(2):135-65

ABSTRACT: Chlorpyrifos (diethyl 3,5,6-trichloro-2-pyridyl phosphorothionate) is a broad-spectrum organophosphorus (OP) insecticide. Anticipated increases in the already extensive use of this compound have prompted this reassessment of its neurotoxicity. Because chlorpyrifos and other OP insecticides are designed to produce acute cholinergic effects through inhibition of acetylcholinesterase (AChE) and some OP compounds can cause OP compound-induced delayed neurotoxicity (OPIDN) via chemical modification of neurotoxic esterase (neuropathy target esterase, NTE), **this review focuses on the capacity of chlorpyrifos to precipitate these and other adverse neurological consequences. Chlorpyrifos exhibits only moderate acute toxicity in many mammalian species, due largely to detoxification of the active metabolite, chlorpyrifos oxon, by A-esterases.** Rats given large doses of chlorpyrifos (sc in oil) have prolonged inhibition of brain AChE, possibly due to slow release of the parent compound from a depot. Associated cognitive and motor deficits return to normal well before recovery of AChE activity and muscarinic receptor down-regulation, as expected from classic tolerance. Controlled studies of OP compound exposures in humans also indicate that cognitive dysfunction requires substantial AChE inhibition. Information is relatively sparse on neurological dysfunction that is secondary to theoretical reproductive, developmental, or immunological effects, but the best available data indicate that such effects are unlikely to result from exposures to chlorpyrifos. In accord with the much greater inhibitory potency of chlorpyrifos oxon for AChE than for NTE, clinical reports and experimental studies indicate that OPIDN from acute exposures to chlorpyrifos requires doses well in excess of the LD50, even when followed by repeated doses of the OPIDN potentiator phenylmethanesulfonyl fluoride (PMSF). Likewise, studies in hens show that subchronic exposures at the maximum tolerated daily dose do not result in OPIDN. Although exposure to chlorpyrifos as a result of normal use is unlikely to produce classical OPIDN, a recent report stated that mild reversible sensory

neuropathy had occurred in eight patients who had been exposed subchronically to unknown amounts of chlorpyrifos. It is not clear whether these cases represent an incorrect linkage of cause and effect, a newly disclosed reversible sensory component of OPIDN, or an entirely new phenomenon. The question of the potential for chlorpyrifos to cause this mild sensory neuropathy could be resolved by the use of quantitative tests of sensory function in animal experiments and/or prospective studies of humans with known exposures to chlorpyrifos.

15.TITLE: Sensory neuropathy associated with Dursban (chlorpyrifos) exposure [published erratum appears in Neurology 1994 Feb;44(2):367]
SOURCE: Neurology 1993 Nov;43(11):2193-6

ABSTRACT: Chlorpyrifos (Dursban) is an organophosphate insecticide with extensive domestic and agricultural applications. It is regarded as safe for these purposes: one report of neurotoxicity is attributed to massive ingestion in a suicide attempt. We report eight people who developed peripheral neuropathy after exposure to exterminator-applied commercial Dursban: five also experienced memory loss and cognitive slowing. Evaluation failed to reveal other causes of neurologic dysfunction; symptoms recurred in one patient following accidental reexposure. We conclude that environmental contact with chlorpyrifos can cause sensory neuropathy and CNS dysfunction and that this agent should be used with caution.

16.TITLE: Chlorpyrifos metabolites in serum and urine of poisoned persons.
SOURCE: Chem Biol Interact 1993 Jun;87(1-3):315-22

ABSTRACT: **Concentrations of parent pesticide and corresponding diethylphosphorus metabolites in blood serum and urine were investigated in persons who had ingested a concentrated solution of organophosphorus pesticide chlorpyrifos.** The organophosphate poisoning was indicated by a significant depression of blood cholinesterase (EC 3.1.1.7 and EC 3.1.1.8) activities. Blood and spot urine samples were collected daily after admission of the persons to hospital. **Chlorpyrifos was detected only in serum samples in a period up to 15 days after poisoning.** In the same samples chlorpyrifos oxygen analogue, chlorpyrifos oxon, was not detected. The presence of diethylphosphorothioate in all serum and urine samples confirmed that part of chlorpyrifos was hydrolysed before its oxidation. The maximum concentrations of chlorpyrifos in serum and of metabolites in serum and urine were measured on the day of admission. The decrease in concentrations followed the first-order kinetics with the initial rate constant faster and the later one slower. In the faster elimination phase chlorpyrifos was eliminated from serum twice as fast ($t_{1/2} = 1.1-3.3$ h) as the total diethylphosphorus metabolites ($t_{1/2} = 2.2-5.5$ h). The total urinary diethylphosphorus metabolites in six chlorpyrifos poisoned persons were excreted with an average elimination half-time of 6.10 ± 2.25 h (mean \pm S.D.) in the faster and of 80.35 ± 25.8 h in the slower elimination phase.

17. TITLE: **Life-threatening organophosphate-induced delayed polyneuropathy in a child after accidental chlorpyrifos ingestion [see comments]**

SOURCE: J Pediatr 1993 Apr;122(4):658-60

ABSTRACT: Life-threatening organophosphate-induced delayed polyneuropathy with transient bilateral vocal cord paralysis occurred in a 3-year-old child. Recovery was slow after prolonged ventilatory support. Patients who recover from serious organophosphate intoxications should be closely monitored for the development of organophosphate-induced delayed polyneuropathy.

18. TITLE: **Immunologic abnormalities in humans exposed to chlorpyrifos: preliminary observations.**

SOURCE: Arch Environ Health 1993 Mar-Apr;48(2):89-93

ABSTRACT: Twelve individuals who were exposed to chlorpyrifos were studied 1-4.5 y following exposure to determine changes in the peripheral immune system. The subjects were found to have a high rate of atopy and antibiotic sensitivities, elevated CD26 cells ($p < .01$), and a higher rate of autoimmunity, compared with two control groups. Autoantibodies were directed toward smooth muscle, parietal cell, brush border, thyroid gland, myelin, and ANA. **Chlorpyrifos exposure was implicated in the immunologic abnormalities reported. The immunologic changes were similar to those reported for other pesticides.**

19. TITLE: **Chlorpyrifos-induced delayed polyneuropathy.**

SOURCE: Arch Toxicol 1991;65(2):150-5

ABSTRACT: **Chlorpyrifos** [0,0-diethyl 0-(3,5,6-trichloro-pyridyl) phosphorothioate] **caused delayed polyneuropathy in man.** Contrary to previous studies, we report here that it also causes delayed polyneuropathy in the hen, the animal model for this toxicity. The minimal neuropathic dose was 60-90 mg/kg p.o., corresponding to 4-6 times the estimated LD50. Consequently, pralidoxime (2-PAM) in conjunction with atropine was necessary to reverse acetylcholinesterase (AChE) inhibition and cholinergic toxicity in hens given high enough doses of chlorpyrifos to cause neuropathy. Chlorpyrifos was slowly absorbed after single oral doses and the threshold of inhibition (greater than 70%) of neuropathy target esterase (NTE), the putative target for delayed neuropathy, was reached within 5-6 days. High AChE inhibition (greater than 90%), however, was measured within hours after dosing because of the higher potency of chlorpyrifos to inhibit this enzyme. In vitro studies showed that chlorpyrifos-oxon, the active metabolite of chlorpyrifos, was 10-20 times more active against AChE than against NTE, confirming the clinical observation. No differences were seen between human and hen enzymes in this respect: Hen and human brain homogenates contain A-esterases which hydrolysed chlorpyrifos to about the same extent in both species. **In conclusion, chlorpyrifos causes delayed polyneuropathy in the hen, as was reported in man. The reasons for previous negative data in the hen are probably due to the relatively lower doses which were used.** Judging from in vitro studies with hen and human

enzymes, there are no differences in the two species as far as their relative sensitivity to delayed polyneuropathy. It is likely that delayed polyneuropathy would develop in both species only after severe cholinergic toxicity requiring aggressive antidotal treatment.

20.TITLE: Potential exposure and health risks of infants following indoor residential pesticide applications.

SOURCE: Am J Public Health 1990 Jun;80(6):689-93

ABSTRACT: Air and surface chlorpyrifos residues were measured for 24 hours following a 0.5 percent Dursban broadcast application for fleas inside a residence. Two of the three treated rooms were ventilated following application. Maximum air concentrations were measured 3-7 hours post- application. Peak concentrations in the infant breathing zone were 94 micrograms/m³ in the nonventilated room and 61 micrograms/m³ in the ventilated room, and were substantially higher than concentrations in the sitting adult breathing zone. Concentrations of approximately 30 micrograms/m³ were detected in the infant breathing zone 24 hours post- application. Surface residues available through wipe sampling were 0.7- 1.6 micrograms/cm² of carpet on the day of application and 0.3-0.5 micrograms/cm² 24 hours post-application. Estimated total absorbed doses for infants were 0.08-0.16 mg/kg on the day of application and 0.04-0.06 mg/kg the day following application, with dermal absorption representing approximately 68 percent of the totals. These doses are 1.2-5.2 times the human No Observable Effect Level (NOEL). **Exposures to cholinesterase inhibiting compounds following properly conducted broadcast applications could result in doses at or above the threshold of toxicological response in infants, and should be minimized through appropriate regulatory policy and public education.**

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The NRA Review of
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Canberra
Australia

7.1 Introduction

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As was stated in the draft report released previously for public comment, the review of chlorpyrifos covered all aspects related to its registration, including approvals of labels and active constituents. Assessments conducted as part of the review considered the existing use pattern of chlorpyrifos in terms of its impact on public health, occupational health and safety (OHS), the environment and trade.

In addition to the above, the NRA considered all public comments that have been received on the draft report and the review of chlorpyrifos. The public consultation process resulted in a re-examination of certain aspects of the draft review report. This re-examination led to a strengthening of the assessment of aggregate exposure, restatement of the environmental warnings on labels, and a further elaboration of the Australian regulatory approach to chlorpyrifos. A summary of the main comments from the public and the NRA responses to these comments is at Attachment 2.

The NRA now proposes to implement a series of interim regulatory measures to manage public health, occupational and environmental risks and to fill the residue data gaps that have been identified.

Certain interim review recommendations require the generation of residue data. Where appropriate this data will be eligible for data protection in accordance with part 3 of the Agvet Code. Those conducting new studies are required to provide appropriate protocols and study designs to the NRA for approval prior to commencing studies.

The following summaries of assessments are intended to provide the reader with a brief overview of the review findings. As the assessment conclusions have remained largely unchanged from those in the draft report, the summaries are repeated from the draft report released previously for public comment with minimal amendment where necessary.

7.2 Main Review Findings

Toxicology and Public Health

Chlorpyrifos is a broad-spectrum organophosphate insecticide that has been used in Australia for over 30 years. Like other organophosphorus compounds, chlorpyrifos kills insects by interfering with the activity of an enzyme (acetylcholinesterase) in the nervous system. This interference causes over-stimulation of the nervous system, and results in rapid twitching and paralysis of muscles. If chlorpyrifos is swallowed, applied to the skin or breathed in by mammals, the effects of poisoning are typical of those seen with other organophosphorus insecticide. Such effects include excessive saliva, rapid breathing, coarse generalised body tremors, secretion of tears, urination, defecation, convulsions, respiratory failure, and death. The severity of signs increases with the amount of exposure but there is an effective antidotal treatment for acute poisoning of chlorpyrifos.

In studies in laboratory animals, chlorpyrifos was rapidly absorbed when swallowed, but did not persist for long periods in the tissues or organs of animals, and passed relatively quickly from the body. Absorption through the skin was relatively poor. Long-term exposure to a low concentration of chlorpyrifos in the diet was without serious consequences in animal studies, although high concentrations resulted in symptoms consistent with those listed above. Chlorpyrifos did not interact with genetic material, and long-term exposure studies in animals provided no evidence that chlorpyrifos can cause cancers in humans. Similarly, exposure to chlorpyrifos had no adverse effects on reproduction. The data on effects of chlorpyrifos in young or developing animals have been reviewed and infants and children are not considered to be at an increased risk from chlorpyrifos products that are used according to label instructions.

In Australia, chlorpyrifos is registered for use in many products including those used in or around the home and garden including termiticide use. These uses may give rise to some exposure of the public, but studies indicate that such exposures do not pose a public health risk. Based on the current uses of chlorpyrifos and with the removal of home garden products containing more than 50g/L chlorpyrifos, and restrictions on indoor spray treatments, it is considered that there should be no adverse effects on public health from the continued use of chlorpyrifos in Australia.

The Australian Market Basket Survey estimates the daily intake of a range of pesticides based on food consumption. In the 1996 survey, the highest exposure to chlorpyrifos in

ATTACHMENT 1 – LIST OF REGISTERED PRODUCTS AND APPROVED ACTIVE CONSTITUENTS (as at 3 August 2000)

NCRIS	PRODUCT NAME	COMPANY NAME
32220	Rentokil Chek-Pest 'C' Domestic Insecticide	Rentokil Initial Pty Ltd
32879	Campbell Pyrinex 500 EC Insecticide	Colin Campbell (Chemicals) Pty Ltd
32881	Campbell Pyrinex 250 WP Insecticide	Colin Campbell (Chemicals) Pty Ltd
32882	CRG Grass-Gard Lawn Insecticide	Chemical Recovery Co Pty Ltd
32883	Chemspray Ant, Spider & Cockroach Killer Insecticide	Garden King Products Pty Ltd
32884	Chemspray Chlorban Insecticide	Garden King Products Pty Ltd
32887	Lorsban 500 EC Insecticide	Dow Agrosciences Australia Ltd
32889	Dursban Micro-Lo Termiticide And Insecticide	Dow Agrosciences Australia Ltd
32890	Dursban PC Termiticide And Insecticide	Dow Agrosciences Australia Ltd
32891	Dursban Turf-500 Insecticide	Dow Agrosciences Australia Ltd
32894	Lorsban 500 WG Insecticide	Dow Agrosciences Australia Ltd
32897	David Grays Chlorpyrifos 200 Termite Sprav	David Gray & Co. Pty Limited
32902	Nufarm Chlorpyrifos 500 EC Insecticide	Nufarm Australia Limited
32903	Nufarm Chlorpyrifos ULV500 Insecticide	Nufarm Australia Limited
32904	Garden King Antkil Granular Insecticide	Garden King Products Pty Ltd
32905	Garden King Peskil C Insecticide	Garden King Products Pty Ltd
32908	Deter Insecticide	Aventis Cropscience Pty Ltd
32909	Chlorfos Insecticide	Aventis Cropscience Pty Ltd
33198	CRG Ban Ant	Chemical Recovery Co Pty Ltd
33589	Watch Cat 8 Month Flea Collar	Friskies Pet Care Pty Ltd
33605	Zodiac Long Life Flea Cat Collar	Novartis Animal Health Australasia Pty Ltd
36396	Watchdog 9 Month Flea Collar	Friskies Pet Care Pty Ltd
36918	Exelpet No Fleas Flea And Paralysis Tick Spray For Dogs	Exelpet Products (A Division Of Effem Foods Pty Ltd)
36919	Exelpet Red 5 Month Flea Collar For Dogs	Exelpet Products (A Division Of Effem Foods Pty Ltd)
36920	Exelpet Red 8 Month Flea Collar For Cats	Exelpet Products (A Division Of Effem Foods Pty Ltd)
38930	Vet-Kem Long Life Flea Cat Collar	Novartis Animal Health Australasia Pty Ltd
38933	Zodiac Long Life Flea & Tick Dog Collar	Novartis Animal Health Australasia Pty Ltd
39222	David Grays Antex Granules	David Gray & Co. Pty Limited
39267	Pyrinex 250 WP Insecticide	Makhteshim-Agan (Australia) Pty Limited
39268	Pyrinex 500 EC Insecticide	Makhteshim-Agan (Australia) Pty Limited
39885	Nufarm Chlorpyrifos PCO Insecticide	Nufarm Australia Limited
39910	Nufarm Chlorpyrifos PCO Micro-Emulsion Insecticide	Nufarm Australia Limited
40117	Vet-Kem Long Life Flea And Tick Dog Collar	Novartis Animal Health Australasia Pty Ltd
40812	Campbell Pyrinex 500 WP Insecticide	Colin Campbell (Chemicals) Pty Ltd
41073	CRG Terminant Plus Ant And Termite Killer	Chemical Recovery Co Pty Ltd
41396	Hvgrain Beetle Bait - Pellets	Hvgrain Pty Ltd

41781	Pyrinex 300 ULV Insecticide	Makhteshim-Agan (Australia) Pty Limited
41818	Addimix Chlorpyrifos Insecticide 500 EC	Addimix Pty Ltd
42032	David Grays Lawn Beetle Granules	David Gray & Co. Pty Limited
42033	David Grays Lawn Beetle Sprav	David Gray & Co. Pty Limited
42039	David Grays PCO Chlorpyrifos 500	David Gray & Co. Pty Limited
42062	Hygrain Beetle Baits	Hygrain Pty Ltd
42081	Monsan Beetle Bait	Monsan Pty. Ltd.
42284	David Grays Chlorpyrifos 500	David Gray & Co. Pty Limited
44005	Chlorpyrifos TGAC	Makhteshim-Agan (Australia) Pty Limited
45068	Brunnings Lawn Beetle Destroyer	Brunnings Garden Products Pty Ltd
45227	Ant-Out Granular Insecticide	Pest Control Technologies International Pty Ltd
45449	Brunnings Lawn Grub Destroyer	Brunnings Garden Products Pty Ltd
45486	Farmoz Strike-Out 500 EC Insecticide	Farmoz Pty Ltd
45518	Country Chlorpyrifos 500 Insecticide	A & C Rural Pty Ltd
46154	Mortein Plus 6 Superbaits	Reckitt & Colman Pty Ltd
46435	Mortein Plus 12 Superbaits	Reckitt & Colman Pty Ltd
46677	Baygon Mothpaper	Bayer Australia Limited (Consumer Care)
47022	Richgro Garden Products Ant Killer	A Richards Pty Ltd
47023	Richgro Garden Products Lawn Beetle Killer	Richgro Garden Products
47528	Crg Lawn Beetle Blitz Insecticide	Chemical Recovery Co Pty Ltd
47538	Suscon Blue Soil Insecticide	Crop Care Australasia Pty Ltd
47760	Master 250 CS Insecticide	Makhteshim-Agan (Australia) Pty Limited
47991	SC Johnson Wax Raid Max 12 Roach Terminators Plus 3 Egg Stoppers	S.C. Johnson & Son Pty Ltd
47992	SC Johnson Wax Raid 6 Ultra Baits	S.C. Johnson & Son Pty Ltd
47993	SC Johnson Wax Raid 18 Ultra Baits	S.C. Johnson & Son Pty Ltd
48029	Dursban Pre-Construction Termiticide	Dow Agrosiences Australia Ltd
48051	David Grays Micro-Lo Chlorpyrifos Termiticide And Insecticide	David Gray & Co. Pty Limited
48069	Davison Chlorpyrifos 500 EC Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
48146	David Grays Pre-Construction Chlorpyrifos Termiticide	David Gray & Co. Pty Limited
48448	Agechem Chlorpyrifos 500 EC Insecticide	Chemag Pty Ltd
48624	Blattanex (Bayer) Cockroach Baits	Bayer Australia Limited (Animal Health)
48625	Cyren PC Insecticide	Cheminova Australia Pty Limited
48662	Richgro Garden Products Slater Killer	A Richards Pty Ltd
48764	Iban 500 EC Insecticide	United Phosphorus Ltd
48770	Farmoz Strike-Out PC Termiticide And Insecticide	Farmoz Pty Ltd
48774	Lief Chlorpyrifos Insecticide	Lief Resources Pty Ltd
48795	Oztec Chlorpyrifos 500 EC Insecticide	Oztec Rural Pty Ltd
48911	Mortein Plus Nest Kill 12 Superbaits	Reckitt & Colman Pty Ltd
48958	Richgro Garden Products Ant, Spider & Cockroach Killer Insecticide	A Richards Pty Ltd
48998	Cyren 500 EC Insecticide	Cheminova Australia Pty Limited
49008	Permakill Insecticide	Flamestar Pty Ltd
49055	Predator 300 Insecticide	Dow Agrosiences Australia Ltd
49165	Summit Chlorpyrifos Insecticide	Sumitomo Australia Ltd

49315	Richgro Garden Products Lawn Beetle And Grub Killer	A Richards Pty Ltd
49399	Hortico Lawn Beetle & Slater Killer Granules	Hortico (Aust) Pty Ltd
49454	Garden King Fix Ant Insecticide	Garden King Products Pty Ltd
49473	Creofos Pre-Construction Termiticide	Gainsleek Pty Ltd
49551	Farmoz Strike-Out 250 WP Insecticide	Farmoz Pty Ltd
49666	Barmac Chlorpyrifos G Granular Insecticide	Barmac Industries Pty Ltd
49760	Garden King Lawn Beetle Bomb	Garden King Products Pty Ltd
49766	Baygon (Bayer) Cockroach Stopper	Bayer Australia Limited (Consumer Care)
49809	Empire Insecticide	Dow Agrosiences Australia Ltd
49816	Barmac Chlorpyrifos Insecticide	Barmac Industries Pty Ltd
49869	4 Farmers Chlorpyrifos 500 Insecticide	4farmers Pty Ltd
49944	Proficid (Bayer) Cockroach Paste	Bayer Australia Limited (Animal Health)
50002	Proficid (Bayer) Cockroach Baits	Bayer Australia Limited (Animal Health)
50232	Farmoz Instinct 300 Cotton Insecticide	Farmoz Pty Ltd
50246	Garden King Fix Ant Granular	Garden King Products Pty Ltd
50283	Termifos Termiticide And Insecticide	Pest Management Solutions (A Division Of Nambla Pty Ltd)
50318	Garden King Grubkil Insecticide	Garden King Products Pty Ltd
50335	Richgro Garden Products Lawn Grub And Beetle Killer Insecticide	A Richards Pty Ltd
50384	Scientific Professional Formulation Insecticide	David Gray & Co. Pty Limited
50387	Qm Profos 500 Termiticide And Insecticide	Quadron Manufacturing Pty Ltd
50388	Qm Chlorpyrifos 500 Insecticide	Quadron Manufacturing Pty Ltd
50416	Suscon Green Soil Insecticide	Crop Care Australasia Pty Ltd
50452	Qm Profos 450 Termiticide And Insecticide	Quadron Manufacturing Pty Ltd
50459	Pest One Termiticide And Insecticide	Pest One Pest Control Products Pty Ltd
50566	David Grays Grubkiller Insecticide	David Gray & Co. Pty Limited
50581	Chlorpyrimax 500 Insecticide	Artferm Pty Ltd
50644	S.C. Johnson Wax Raid Maxkill. The Total Cockroach System	S.C. Johnson & Son Pty Ltd
50740	Baygon (Bayer) Cockroach Stopper Killing Gel	Bayer Australia Limited (Consumer Care)
50751	Bar 500ec Insecticide	Sanonda (Australia) Pty Ltd
50753	Optem Pre-Construction Termiticide	Pest Control Technologies International Pty Ltd
50754	Optem 500 Termiticide And Insecticide	Pest Control Technologies International Pty Ltd
50845	Exelpet Fleaban Red 8 Month Flea Collar For Cats	Exelpet Products (A Division Of Effem Foods Pty Ltd)
50931	Protector 500 EC Insecticide	P M Young (Nsw) Pty Ltd
50956	Creofos Pre-Construction - Post-Construction Termiticide & Insecticide	Gainsleek Pty Ltd
51044	Protector 450 Termiticide And Insecticide	P M Young (Nsw) Pty Ltd
51053	Chemturf Argenstem Turf Insecticide	Chemturf Pty Ltd
51107	Suscon Ultra Soil Insecticide	Crop Care Australasia Pty Ltd
51140	Exelpet Fleaban No Fleas Flea & Paralysis Tick Spray For Dogs	Exelpet Products (A Division Of Effem Foods Pty Ltd)
51151	Country Pre-Construction/Post-Construction Termiticide And Insecticide	A & C Chemicals Pty Ltd
51180	Qm Prefos Pre-Construction Termiticide	Quadron Manufacturing Pty Ltd
51190	Chemag Chlorpyrifos 500 Insecticide	Chemag Pty Ltd
51211	Lorsban 750 WG Insecticide	Dow Agrosiences Australia Ltd

51258	Davison Low Odour Chlorpyrifos 500 EC Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
51286	Snare Termiticide	Dow Agrosiences Australia Ltd
51306	Davison Chlorpyrifos 300 ULV Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
51372	Australian Fine Chemicals Pro-Tek Pre-Construction Termiticide	Jenny Richardson T/As Australian Fine Chemicals
51404	Cropro Optem EC 500 Insecticide	Pest Control Technologies International Pty Ltd
51448	Superfos Termiticide And Insecticide	R.V. Pidgeon
51473	Chlorfos ULV Insecticide	Aventis Cropscience Pty Ltd
51513	Cyren 500 WP Insecticide	Cheminova Australia Pty Limited
51524	Y-Tex Warrior Insecticidal Cattle Ear Tags	Flycam Pty Ltd
51558	Pif Paf Nest Kill Cockroach Baits	Reckitt & Colman Pty Ltd
51563	Generifos 300 Ec/ULV Insecticide	Grow Choice Pty Limited
51566	O'briens Beetle Bait	O'briens Trading Pty Ltd
51567	Optem Pt 45 Termiticide And Insecticide	Pest Control Technologies International Pty Ltd
51592	Prefos Termiticide	Chemag Pty Ltd
51624	Prowler 300 Insecticide	Chemag Pty Ltd
51626	Generex Chlorpyrifos 500 EC Insecticide	Generex Australia Pty Ltd
51727	Pest One Agricultural Insecticide	Pest One Pest Control Products Pty Ltd
51769	Garrards Ant Killer 50	Garrard's Pesticides Pty Ltd
51792	Jwk Chlorpyrifos 450 Termiticide And Insecticide	Jwk Services Pty Ltd
51840	Voodoo 500 Insecticide	Sipcam Pacific Australia Pty Ltd
51875	Pidgeon's Pest Controller 500 Termiticide And Insecticide	R.V. Pidgeon
51897	Cropro Eclipse 300 Insecticide	Pest Control Technologies International Pty Ltd
51963	Prottem Termiticide And Insecticide	Pest Control Technologies International Pty Ltd
51965	Pro-Tek Termiticide & Insecticide	Jenny Richardson T/As Australian Fine Chemicals
51983	Chlorpyrifos Tgae	Unisun Chemicals Pty Ltd
52023	Davison Banshee 300 Duo Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
52037	Nomix Chlorpyrifos 500EC Insecticide	Nomix Australia Pty Ltd
52038	Kensban 500ec Insecticide	Chin-Huat Teo For Kenso Corporation (M) Sdn Bhd
52045	Cyren 300 ULV/EC Insecticide	Cheminova Australia Pty Limited
52046	Promex Peo Termiticide & Insecticide	Lawlor Chemical Industries Pty Ltd
52049	Nufarm Pirate 300 Insecticide	Nufarm Australia Limited
52167	Munns Lawn Grubs, Lawn Beetle Grubs & Slater Killer With Long Life Organically Advanced Weta-Lawn	Munns Lawn Co Pty Ltd
52235	Farmoz Cyren 500 WP Insecticide	Farmoz Pty Ltd
52289	Exelpet Fleaban 8 Month Flea Collar For Cats	Exelpet Products (A Division Of Effem Foods Pty Ltd)
52344	Cropro Zigma 300 Insecticide	Pest Control Technologies International Pty Ltd
52564	David Grays Antex 50 Granular Professional Insecticide	David Gray & Co. Pty Limited
52585	Termispray 500 Insecticide And Termiticide	Termiproducts Pty Ltd

52596	United Farmers Chlorpyrifos 500 Insecticide And Termiticide	United Farmers Cooperative Company Ltd
52746	Voodoo 300 Insecticide	Sipcam Pacific Australia Pty Ltd
52766	Generex Distribution Generifos 500 EC Insecticide	Grow Choice Pty Limited
52822	Davison Battleaxe 300 Duo Insecticide	Davison Industries An Activity Of Joyce Rural Pty Ltd
52870	Snare Termiticide And Insecticide	Dow Agrosiences Australia Ltd
52976	Crop Care Chlorpyrifos 500 EC Insecticide	Crop Care Australasia Pty Ltd
44005	Chlorpyrifos TGAC	Makhteshim-Agan (Australia) Pty Limited
44111	Chlorpyrifos TGAC	Dow Agrosiences Australia Ltd
44112	Chlorpyrifos TGAC	Dow Agrosiences Australia Ltd
44113	Chlorpyrifos TGAC	Dow Agrosiences Australia Ltd
44160	Chlorpyrifos TGAC	Dow Agrosiences Australia Ltd
46670	Chlorpyrifos TGAC	David Gray & Co. Pty Limited
46796	Chlorpyrifos TGAC	Australian Generics Pty Ltd
46888	Chlorpyrifos TGAC	Gharda Australia Pty Ltd
47155	Chlorpyrifos TGAC	Excel Industries (Australia) Pty Ltd
47254	Chlorpyrifos TGAC	Sanonda (Australia) Pty Ltd
48077	Chlorpyrifos TGAC	Lief Resources Pty Ltd
48459	Chlorpyrifos TGAC	Davison Industries An Activity Of Joyce Rural Pty Ltd
48521	Chlorpyrifos TGAC	Cheminova Australia Pty Limited
48643	Chlorpyrifos TGAC	David Gray & Co. Pty Limited
49124	Chlorpyrifos TGAC	Dow Agrosiences Australia Ltd
49340	Chlorpyrifos TGAC	Dow Agrosiences Australia Ltd
50886	Chlorpyrifos TGAC	Becot Pty Ltd T As Intrade
51235	Chlorpyrifos TGAC	Gharda Australia Pty Ltd
51239	Chlorpyrifos TGAC	Unisun Chemicals Pty Ltd
51983	Chlorpyrifos TGAC	Unisun Chemicals Pty Ltd

ATTACHMENT 2: SUMMARY OF RESPONSES TO THE PUBLIC RELEASE OF DRAFT REVIEW REPORT

In January 2000, the draft report from chlorpyrifos ECRP review was released for public comment. Consistent with the established practice, extensive consultation was conducted with stakeholders in Commonwealth and State authorities and industry prior to the release of the draft report.

The release of the draft report was widely publicised and written notices were sent to all who had expressed interest in or who had participated in the review thus far. The report was available to the public either via the Internet or as a printed copy upon request from the NRA. The public comment phase was originally intended for two months. However due to sustained public and media interest in chlorpyrifos, comments were received and considered beyond the two-month period.

In addition to calling for comments on the actual report, stakeholders were also requested to provide a commitment to undertake trial work to generate the necessary residues data. Residues data are required for the NRA to be satisfied that the continued use of chlorpyrifos does not pose an unacceptable risk to the people using anything containing its residues and that it does not unduly prejudice trade.

In response to the release of the draft report some 40 responses were received from individual members of the public, activist and user groups, chemical & other industry, environmental associations and Commonwealth and State government and overseas regulatory agencies. Submissions also included those from organisations producing, processing or associated with the following commodities: avocado, tropical fruits, vegetables, cotton, tobacco, pineapple, sugarcane, pome and stone fruit, citrus, longans, custard apple, ginger, hops and olives.

As expected, most comments centred on the proposed restrictions and the identified residue data gaps. Significant comments were also received on the subjects of exposure to chemicals in general and to chlorpyrifos in particular. The recent United States Environmental Protection Agency (USEPA) actions on chlorpyrifos triggered substantial public and media interest in the review. The NRA has acknowledged this interest by re-examining the relevant components of its review to ensure that the continuing use of chlorpyrifos in Australia meets the legislative criteria for safety and performance.

The following summary describes the main issues raised and concerns expressed by the respondents to the ECRP review of chlorpyrifos. Where several respondents have similar comments and concerns these have been grouped together for the ease of presentation. Views and opinions expressed remain those of the respondents and not those of the NRA or the assessing agencies. Wherever possible any assessable data accompanying public submissions has been assessed by the relevant agency advising the NRA. In the following summary, public comments and concerns are presented in normal font while the NRA responses to those concerns or the NRA proposals to address those concerns are in *italics*.

User industry views on chlorpyrifos

Most respondents from grower associations highlighted the important role that chlorpyrifos plays in their total pest management strategies.

Chlorpyrifos is a valuable insecticide in the stone fruit industry. In stone fruit, 70% of growers use chlorpyrifos in IPM programs to control such pests as light brown apple moth, thrips, dimple bug, bryobia mite, earwig, rose weevil, oriental fruit moth, garden weevil and white ants. Chlorpyrifos is particularly important in this industry for the control of San Jose Scale. In the tobacco industry chlorpyrifos is the only pre-plant insecticide currently registered for the control of certain soil borne insects.

The importance of chlorpyrifos in insect control in bananas in both NSW and QLD was highlighted. The most common application method is for bunch spraying of bananas. The control of bunch pests such as bud moth, flower thrips and rust thrips is critical to producing a marketable product. Alternative chemicals do exist, however, chlorpyrifos is preferred as it provides long-term broad spectrum control of all main bunch pests.

Chlorpyrifos is critical for the control of cutworms and crickets in vegetables as well as scale and ant control in mangoes.

Chlorpyrifos is widely used for ant control since the phasing out of organochlorine pesticides. It is known to provide efficacious ant control in longans, citrus, cucurbits, mangoes, custard apples and pineapples. It has both good contact action and a degree of residual action against a range of ant species. There appears to be no satisfactory alternatives to chlorpyrifos for ant control in fruit trees.

According to the Department of Natural Resources and Environment in Victoria, canola growers have increased their use of chlorpyrifos for control of false wireworm, used mainly prior to sowing.

The Avocado Growers Association of Western Australia states that they are a minor user of chlorpyrifos. While alternatives to chlorpyrifos exist for control against latania scale and ivy leafroller in avocados the alternatives have concerns. Oil sprays are moderately effective but can be phyto-toxic to trees in hot weather. The association further states that methidathion is used as an alternative however this is highly toxic and damaging to beneficial insects. Although alternatives are being investigated, these will probably need to be used in rotation with chlorpyrifos to obtain optimal control.

A respondent from the custard apple industry stated that chlorpyrifos is used as a trunk spray in custard apples for control of ants. The alternative to chlorpyrifos is methidathion which is disruptive to IPM control programs.

The NRA would consider the continued use of chlorpyrifos in any crop/use situation on the current label subject to the filling of data gaps and the implementation of restrictions designed to mitigate risks identified during the assessment phase. If uses are not supported by data and concerns remain, then such uses will not be retained. The longer term decisions on the use of chlorpyrifos are expected to be made when additional data has been submitted and assessed.

Domestic uses of chlorpyrifos - public health issues

Several respondents commenting on the domestic uses of chlorpyrifos question the apparent lack of attention to the exposure and effects on children and other sensitive individuals. Some respondents identified domestic use of chlorpyrifos as a risk to children and still others were of the view that chlorpyrifos is a principal contributor to multiple chemical sensitivity in certain individuals. One respondent claimed flea collars containing chlorpyrifos as being inherently dangerous and that children would be at risk if they chew or suck the collar.

Some respondents argued that the sensitive individuals would suffer greater damage from environmental and domestic exposure to chlorpyrifos and the absence of a pesticide illness reporting program in Australia would constrain the introduction of the appropriate regulatory responses.

The NSW EPA commented that the proposed statement to limiting householder use of chlorpyrifos should focus on the restriction of its use by householders, and not just the home garden applications.

The NRA does not share the view that the attention devoted to public safety in this review is lacking in any respect. Following its review of chlorpyrifos, the NRA has instituted a range of risk-mitigating measures aimed at safeguarding public health. These measures focus on areas of probable risk of public exposure and are consistent with the accepted standards of public safety.

For instance, specific regulatory action is pending on products that are identified as being non-compliant with the NHMRC/NRA guidelines relating to public health. Further labelling restrictions have been introduced to curtail residential uses of chlorpyrifos that are identified as potential sources of risk to the public.

- *All liquid products whose concentration of chlorpyrifos exceeds 5% that are supplied in home garden pack sizes (1 Litre and below) are slated for withdrawal from householder use.*
- *A warning to the effect that "This product is too hazardous for use by householders. Householders must not use this product in or around the home." will appear on labels of chlorpyrifos products of concentration greater than 5%. This restriction is intended to prevent concentrated chlorpyrifos products intended for PCO use, from being used by householders.*
- *A further statement will strengthen the regulation of indoor spray applications of chlorpyrifos.*
- *Safety directions have been reconsidered for all chlorpyrifos products and have been strengthened for the most.*
- *The review has required adequate ventilation (until complete dryness of treated areas) before reoccupying or entering treated areas. This applies to pre- and post construction termiticides and general pest control treatments.*

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- *The actual data on food intake contained in the Australian Market Basket Survey of 1996 (the latest available) indicate that the intake of chlorpyrifos remains low and not considered to pose a risk to public health.*

Based on the available information on the toxicity and release properties of flea collars, the TGA considered that the risk associated with the use of chlorpyrifos flea collars was not significant for both children and adults.

On the comment regarding sensitive individuals; it is not possible to determine the role of chlorpyrifos in causing complex clinical effects in sensitive individuals incidentally exposed to indeterminate amounts of this compound. However it is recognised that long-term neurological effects have been reported in workers repeatedly exposed to organophosphate compounds. While the role of chemical exposure in the aetiology of these clinical effects has not been conclusively determined the NRA adopts a conservative approach to the regulation of organophosphate pesticides, in the interests of maintaining public and occupational health and safety. The use of plasma cholinesterase inhibition, the most sensitive indicator of toxicity to set public health standards for chlorpyrifos, is a case in point.

The issues raised on the exposure to chlorpyrifos via food, environmental and household exposures appeared in some instances to concern the use patterns in the USA. However, under Australian use conditions, the Australian Market Basket Survey has found very low chlorpyrifos food residues in the average diet. Other routes of exposure arising from the use of chlorpyrifos according to labels is considered by the appropriate authorities not to pose an unacceptable risk to the public.

Some respondents noted the lack of an adverse effects reporting register for pesticide exposures in Australia. Such data, were they available, would be very useful in recording poisoning incidents that arise from the use of chlorpyrifos, and to determine the nature of such exposures.

In view of the NSW EPA comment, an appropriate statement will be incorporated on product labels to include both home garden and other domestic uses of chlorpyrifos.

In conclusion, following a comprehensive review the public health aspects of chlorpyrifos the appropriate authorities concluded that based on the current uses of this compound, with the removal of home garden products containing more than 5% chlorpyrifos, and restrictions on indoor spray applications, it is considered that there should be no adverse effects on public health from the continued use of chlorpyrifos in Australia.

The Australian review of chlorpyrifos vis-a-vis the US EPA regulatory actions

A major issue raised during the public comments phase has been the regulatory actions of the United States Environmental Protection Agency (US EPA) on chlorpyrifos. Significant public comment revolved around the differences of Australian regulatory approaches for chlorpyrifos in comparison to those of the US EPA.

There are a number of technical and policy approaches to the regulation of pesticides that vary between different national authorities, and these have contributed to some differences in risk assessment and management strategies for chlorpyrifos in the USA as compared with Australia.

For chlorpyrifos, Australian regulators have reviewed the extensive database of toxicology studies conducted in animals and human volunteers. The public health standards in Australia have been established using the most sensitive biological effects of chlorpyrifos and based on results from studies in human subjects, and this removes the added uncertainty that comes from the use of data from animal studies. The Australian Acceptable Daily Intake (ADI) value is lower than the international equivalent established by the World Health Organisation in 1999. The data on effects of chlorpyrifos in young or developing animals have been reviewed and infants and children are not considered to be at an increased risk from chlorpyrifos products that are used according to label instructions. Chlorpyrifos residues in the Australian diet are very low and do not pose a public health risk. Household products that contain chlorpyrifos must meet strict guidelines on packaging and formulation to ensure that the risk to the public from such products continues to be low. For more hazardous chlorpyrifos products such as those used by licensed pest control operators, changes have been recommended in availability, packaging and labelling. As a result products whose toxicity makes them inappropriate for use by householders (products that contain greater than 50 g/L chlorpyrifos) will be restricted to reduce any public health risks.

The US EPA have applied extra uncertainty factors when establishing public health standards due to their use of animal studies and as mandated by the Food Quality Protection Act (FQPA). As a result, the health standards established by the US EPA (including the Reference Dose and the Population Adjusted Dose) are lower than the Australian ADI. One of the outcomes of the US EPA review is that registrants in the USA have arrived at a negotiated position that includes the withdrawal of most residential and a few agricultural uses of chlorpyrifos products over the next five years.

Short-term dietary risk considerations

A comment was made about the US restrictions regarding chlorpyrifos use on agricultural uses such as apples, tomatoes and grapes. The US EPA are discontinuing the use of chlorpyrifos on tomatoes, restricting use on apples, and reducing the tolerance (MRL) on grapes. These actions appear to have been motivated solely by short-term dietary intake considerations.

In the USA, the chronic dietary food risk did not exceed the EPA's level of concern for any of the population groups. The risks identified arose from acute dietary intake and resulted from the use of chlorpyrifos on apples (residues resulting from post-bloom uses), grapes (residues primarily on imported crops) and fresh tomatoes. The NRA has also noted that the dietary estimates for these commodities were reached using probabilistic modelling methods (Monte Carlo) at the 99.9th percentile for the most highly exposed population sub-group.

An assessment conducted using the available Australian consumption data for apples indicated that the acute dietary intake of chlorpyrifos in apples was low in relation to the applicable Australian public health standard - the acute reference dose (ARfD) of 0.01

mg/kg bw/day. The intake of chlorpyrifos at the 97.5 percentile food intake level when expressed as a fraction of the ARfD was less than half for 2-6 years old children; and less than one-fifth for the general population (7 years and above) and was not considered to pose a public health risk.

Environmental Warnings

A number of respondents raised concern over the proposed environmental warning statements. Concerns were raised by a number of State agencies noting that the wording of some of these statements would need to be amended in order for them to be enforceable. Others noted that certain statements required re-wording in order to clarify the purpose of these statements.

Amongst the key issues raised by the State authorities relate to enforceability of proposed label warnings and the need for a clear distinction between mandatory requirements and advisory information. These comments were referred to Environment Australia for consideration.

In conjunction with Environment Australia, the NRA has refined the environmental warnings wherever possible by making a clearer distinction between the advisory and mandatory statements. Where appropriate alternative risk management/mitigation measures have also been incorporated, with emphasis on environmental safety outcomes.

Buffer Zones

Many respondents expressed concern over the practicality of mandatory physical distances as buffer zones in certain use situations. Some of the issues raised were as follows:

- No allowances have been given for orchard areas situated close to human dwellings;
- New practices are being undertaken in certain industries to reduce spray drift. Studies have shown that a single row of trees can reduce up to 80% of spray drift, as an alternative to establishing particular physical distances or no-spray zones;
- The apple and pear industry stated that they recommend a row of trees or hail net curtains as having the same effect of capturing potential drift, thereby providing the protection necessary for sensitive areas;
- A clearer definition was required for droplet sizes, as well as definitions for upwind and downwind buffers and including what constitutes a sensitive area.

Having considered the above, the label statements have been modified to include additional advisory information with respect to drift reduction in addition to references to industry best practice manuals. It is recognised that alternative solutions such as tree rows or hail netting have the same effect on spray drift reduction as mandatory distances and label language has been incorporated to reflect this.

Label restraints need to be strengthened by incorporating statements that are designed to minimise spray drift and environmental contamination. Users, particularly in urban areas, should be better educated in order to minimise the frequency of surface water contamination and incidents involving aquatic and terrestrial wildlife.

Residue Limits

Crop protection uses of chlorpyrifos were the primary focus of the residues evaluation. Non-food uses, plus a recently-registered direct veterinary treatment were considered, however no changes to existing animal commodity MRLs resulted from the assessment of these products.

In the majority of crop situations, existing MRLs were established on minimal Australian data or on overseas data in support of an Australian use pattern. Where appropriate residue data was inadequate or missing, it was considered that such use patterns were not supported by contemporary regulatory standards. The existing MRLs for certain commodities (such as asparagus, bananas, brassica vegetables, cereals, citrus fruits, grapes, oilseeds (except cotton), pineapples, pome fruits, stone fruits, sugar cane, tomatoes, tree nuts and vegetables (excluding those mentioned above) will become temporary until appropriate data are submitted and evaluated).

There are several crops and processed crop commodities for which residues data are either deficient or lacking (e.g. cereal grains, legume animal feeds, pastures, grapes [pomace and marc] and sugar cane). In view of the data deficiencies, the existing animal commodity MRLs will become temporary until data are provided in support of the feed commodities which have been identified.

Given the wide range of registered uses for vegetables, the current entry for vegetables (MRL of *0.01 mg/kg) is recommended to be deleted and replaced with entries for specific vegetable crops. However, until specific uses on product labels are supported and the appropriate data generated and assessed, the vegetable MRL will remain temporary.

7.3 Proposed Regulatory Action

As outlined above, the assessments conducted as part of the review point to possible public health and environmental concerns associated with the use of chlorpyrifos. The NRA aims to address these concerns using the proposed regulatory actions for chlorpyrifos.

The toxicology assessment indicated that some formulations of chlorpyrifos, currently accessible to householders may pose an unacceptable risk to these users. Accordingly, a series of restrictions and risk mitigating measures for these products have been recommended. The re-examination of the aggregate exposure to chlorpyrifos, revealed that the current labels do not specifically preclude indoor broadcast applications. The labels have been strengthened to provide clear directions to users/applicators to prevent indoor broadcast applications of chlorpyrifos. Environmental concerns warrant new and improved warnings on chlorpyrifos product labels. The residues assessment has identified that for some use patterns there are little or no data on which to establish/maintain residue standards.

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The public consultation process enabled the NRA to obtain detailed comment on the proposed regulatory action for chlorpyrifos and commitments to generate the required data from stakeholders. In the light of stakeholder comments, the NRA also made further refinements to its regulatory approach for chlorpyrifos. Commitments to provide the required residue data have been accepted on the understanding that these will be submitted within a mutually acceptable time frame. These initial commitments notwithstanding, failure to provide data for whatever reason would mean that the NRA will have insufficient information to satisfy itself of the absence of an undue hazard associated with the continued use of chlorpyrifos. The NRA would therefore be obliged to take further regulatory measures that could include the cancellation of registrations of products containing this chemical.

7.4 Changes to Labels and Conditions of Registration

The following changes will apply as appropriate to the labels and registered details of products containing chlorpyrifos.

Recommendation 1: First Aid and Safety Directions

First Aid Instructions

No changes to First Aid Instructions have been proposed for chlorpyrifos or products containing chlorpyrifos.

Safety Directions (SD)

Table 1. Current FAISD Handbook entries
(Including recommended amendments in **bold text**)

Current entry	TGA recommendation	NOHSC recommendation
IG BA 5 g/kg or less in a plastic labyrinth	No changes to existing SD	No changes to existing SD
BL 500 g/L or less	No changes to existing SD	Remove entry from FAISD Handbook
DL 30-50 g/kg	No changes to existing SD	No changes to existing SD
EC for termiticide application except as otherwise specified	No changes to existing SD	Remove entry from FAISD Handbook
EC 500 g/L or less EC ME 500 g/L or less (termiticide application by hand spray)	No changes to existing SD	Replace 295 (elbow-length (nominate other specific material) gloves) with 294 (elbow-length PVC gloves) Remove "by hand spray"
EC ME 200 g/L or less	No changes to existing SD	No changes to existing SD
EC greater than 200 g/L, 500 g/L or less EC ME greater than 200 g/L, 500 g/L or less ULV 500 g/L or less WP 500 g/L or less	Add 161, 162 Will irritate the eyes and skin	Add LC greater than 200 g/L, 500 g/L or less No changes to existing SD

GR 100 g/kg or less, in controlled slow release form	No changes to existing SD	No changes to existing SD
HG GR 50 g/kg or less	No changes to existing SD	No changes to existing SD
HV ME 50 g/L or less	No changes to existing SD	No changes to existing SD
LD 10-20 g/L	Add AC 10-20 g/L No changes to existing SD	No changes to existing SD
SR 10 g/kg or less	No changes to existing SD	No changes to existing SD
SR (impregnated paper)	No changes to existing SD	No changes to existing SD
SR (pet collar)	No changes to existing SD	No changes to existing SD
SR 140 g/kg	No changes to existing SD	Replace 300 (half face respirator) with 292b 294 (cotton overalls buttoned to the neck and wrist (or equivalent clothing) and elbow-length PVC gloves); Replace 364 (respirator ...) with 361 366 (gloves and contaminated clothing)
WG 750 g/kg or less	No changes to existing SD	No changes to existing SD
WG ST 750 g/kg or less when packed in sealed water soluble bags	No changes to existing SD	No changes to existing SD

Table 2. New FAISD handbook entries

New entry	TGA recommendation	NOHSC recommendation
ME gel 16 g/L (microencapsulated compound in a gel formulation)	160 161 210 211 351 May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.	No additional PPE required
HG ME PA 16 g/L (microencapsulated compound in a paste formulation)	160 161 210 211 351 May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.	No NOHSC advice required
BA 20 g/kg	160 161 210 211 351 May irritate the eyes and skin. Avoid contact with eyes and skin. Wash hands after use.	When using the product wear chemical-resistant gloves (*)
EC 225 g/L or less with dichlorvos 250 g/L or less in liquid hydrocarbon		To be finalised during dichlorvos ECRP review

Note: Bold text in Table 1 above indicates amendments to current First Aid Instructions and Safety Directions Handbook entries for these formulation types. For complete Safety Directions for the respective formulation type, refer to the current edition of the Handbook.

(*) NOHSC advice for PPE was (279, 283, 290, 294, 360, 361, 366) "When using the product wear elbow-length PVC gloves. After each day's use wash gloves and contaminated clothing". The PPE specified in the table above is considered appropriate for this product.

Recommendation 2: Home Garden and Indoor Use of Certain Chlorpyrifos Products - Public Health Implications

The toxicology assessment has identified that there are a number of emulsifiable concentrate (EC) and/or liquid concentrate (LC) formulations registered for use in

domestic, home garden and/or lawn areas. Most of these formulations contain chlorpyrifos at concentrations between 240 and 500 g/L, and are available in home garden pack sizes (1 litre or less). The toxicity of these formulations is such that they do not comply with NRA Guidelines for pesticides used by householders.

The NRA guidelines "Guidelines for pesticides used by householders, Ag Requirements Series, Part 3, Toxicology, Appendix 3-1" indicate that pesticides for household, home garden or domestic use should be relatively harmless or capable of causing only mild illness if poisoning occurs. They should not cause irreversible toxicity on repeated exposure, nor require the use of safety/personal protective equipment that is not readily available to householders. It is generally regarded that liquid formulations containing chlorpyrifos at 50g/L or less are acceptable in terms of their compliance with the NRA guidelines.

The following risk-mitigation measures are to reduce public health risks from the use of these products:

1. Registrations and label approvals of all EC and LC products based on the Code of Practice for Labelling Home Garden and Domestic Pest Control Products (Home Garden Labelling Code) and that contain chlorpyrifos in amounts greater than 50 g L shall be cancelled.
2. Labels of all emulsifiable concentrate (EC) and liquid concentrate (LC) products containing chlorpyrifos in amounts greater than 50 g/L and in pack sizes of 1 Litre or less must include statements *"This product is too hazardous for use by householders. Householders must not use this product in or around the home."*
3. Registrations and label approvals of all EC and LC products containing chlorpyrifos in amounts greater than 50 g/L and in pack sizes of 1 Litre or less that do not include the label statements *"This product is too hazardous for use by householders. Householders must not use this product in or around the home."* shall be cancelled.

Indoor use of chlorpyrifos

It has become apparent in the course of re-examination of the aggregate exposures to chlorpyrifos, that the current labels do not specifically preclude indoor broadcast applications. While the product labels supported crack and crevice treatments, they did not contain statements to prevent indoor broadcast use. In order to provide clear instructions to users/applicators, specific statements will be placed on labels of certain products as follows:

4. Label of any product containing chlorpyrifos at concentrations above 5% that can be applied inside buildings as a spray, must contain the statements *"DO NOT apply inside buildings except as a crack and crevice treatment. DO NOT apply to surface areas such as interior floors or walls."*

Recommendation 3: Label Warnings for Occupational Health and Safety

The following re-entry period statements must be included on product labels as appropriate:

(a) Field crops, tree crops and vines: Do not allow entry into treated crops until spray deposits have dried. If prior entry is required, limit duration of entry and wear cotton overalls buttoned to the neck and wrist (or equivalent clothing) and chemical resistant gloves. Clothing must be laundered after each day's use.

(b) Greenhouses: Do not allow entry into greenhouses until spray deposits have dried and treated areas are adequately ventilated. If prior entry is required, limit duration of entry and wear cotton overalls buttoned to the neck and wrist (or equivalent clothing), chemical resistant gloves and half-facepiece respirator. Clothing must be laundered after each day's use.

(c) Cotton chippers: Do not allow entry into treated areas until spray deposits have dried. After this time, wear shoes, or boots, socks, long trousers, long sleeved shirt, gloves and hat.

(d) Pre-construction termite control

Suspended floors: DO NOT allow entry until treated areas are completely dry (normally 3-4 hours)

Concrete slabs: cover immediately after treatment with a moisture membrane

(e) Post-construction termite control and general pest control

Re-entry to treated areas: DO NOT permit re-occupation of any premises until treated areas are completely dry (normally 3-4 hours) and adequately ventilated.

Recommendation 4: Label Warnings for Environmental Protection

In order to avoid run-off and drift after application as well as reduce other risks to the environment from the use of chlorpyrifos, the following statements must be incorporated on product labels as appropriate:

For termiticide products:

10. VERY HIGHLY TOXIC TO FISH AND AQUATIC INVERTEBRATES. Rinse waters, and run-off from treated areas MUST NOT enter drains or waterways. For under-slab treatments, the moisture membrane MUST be installed immediately after treatment. Do NOT apply to waterlogged soils. Do NOT apply if heavy rains are expected to occur within 48 hours of application.

11. HIGHLY TOXIC TO BIRDS. Do NOT treat fill unless it has been placed back in the trench to form the chemical soil barrier.

For agricultural products:

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1. The prohibition for human consumption of chlorpyrifos treated grapevine leaves should be removed from labels.

2. For cotton the following withholding periods are required:

- (i) DO NOT harvest for 4 weeks after application
- (ii) DO NOT graze or cut for stockfood for 4 weeks after application

3. For major animal feeds (cereal grains, legume animal feeds, grasses, grass-like plants, pastures and other forages/forage crops) the following grazing restraint applies:

- (i) DO NOT graze or cut for stockfood for 2 days after application

Recommendation 6: Changes to the MRL Standard

Table 7X: Chlorpyrifos MRLs: Proposed Changes from Review

Commodity	MRL Prior to review	Amended MRL	Comment
Asparagus	0.5	T0.5	HRDC to provide indication of interest
Avocado	0.5	0.5	No change to the current MRL and no additional data required.
Banana	T0.5	T0.5	Data required for bunch spray use pattern
Brassica (cole or cabbage) vegetables. Head cabbages. Flowerhead brassicas	0.5	T 0.5	Further data being evaluated. Commitment obtained from registrant to conduct new studies.
Cassava	*0.02	T*0.02	Proposed to be grouped under 'Root vegetables' classification. Further data being evaluated.
Celery	T5	T5	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Cottonseed	0.05	0.05	No change to the current MRL and no additional data required.
Cottonseed oil, crude	0.2	0.2	No change to the current MRL and no additional data required.
Cattle, Edible offal of	2		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Temporary MRL for Edible offal (mammalian)
Cattle meat [in the fat]	2		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Temporary MRL for meat (mammalian) [in the fat].
Edible offal (mammalian)		T0.1	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Meat [mammalian] [in the fat]		T0.5	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Cereal grains [except sorghum]	0.1	T0.1	New data to be evaluated. Registrant commitment to conduct new studies obtained.
Citrus fruits	0.5	T0.5	Further data to be evaluated. MRL will remain as temporary pending evaluation of data.
Dried fruits	2		MRL to be deleted and replaced by Temporary MRL for appropriate Codex Commodity classification, i.e. Dried Grapes
Grapes	1	T1	Existing MRL proposed to be deleted and replaced by Temporary MRL. Registrant commitment to conduct new studies obtained.

- 12. HIGHLY TOXIC TO BIRDS AND REPTILES. VERY HIGHLY TOXIC TO FISH AND AQUATIC INVERTEBRATES.
- 13. DO NOT re-apply to the same crop within 7 days (unless specifically recommended in the directions for use)
- 14. Spray drift may occur under adverse meteorological conditions or from certain spray equipment. Do NOT allow spray to drift onto sensitive areas including, but not limited to, natural streams, rivers or waterways and human dwellings. A spray drift management strategy such as those in the 'Best Management Practices Manual for Cotton Growers' or the 'Pilots and Operators Manual' should be applied.

Options for minimising drift to sensitive areas include not spraying within a certain distance of sensitive areas when the wind is blowing towards them (see table for guidance) or ensuring that drifting spray will be intercepted by a catching surface such as a row of shelter trees, an unsprayed row of orchard trees, or hail netting.

Situation	Recommended buffer distance (m)
Orchard (dormant trees, citrus, large trees)	30
Cotton (aerial application)	300
Other crops (aerial application)	100

- 15. DO NOT apply if heavy rains or storms that are likely to cause surface runoff are forecast in the immediate area within two days of application.
- 16. DO NOT apply when irrigating, or to waterlogged soil, or while water remains on the surface or in furrows, unless tailwater is captured on farm.
- 17. DO NOT allow contaminated runoff water from treated paddocks to enter adjacent areas or water bodies. Runoff contaminated by irrigation events (tailwater) and a 25 mm rain storm should be captured on farm for two days after application.
- 18. All labels of chlorpyrifos granular ant control products registered for use in the home garden should carry the following statements:

Do NOT heap granules.
 These granules may kill birds if ingested.
 Do NOT feed granules or otherwise expose to wild or domestic birds.

Recommendation 5: Label Statements Associated with Residues and Maximum Residue Limits

The following statements apply to product labels as appropriate.

Commodity	MRL Prior to review	Amended MRL	Comment
Dried grapes (currants, raisins, and sultanas)		T2	Temporary MRL established for appropriate Codex Commodity classification, i.e. Dried Grapes.
Eggs	0.01	T0.01	Further data to be evaluated. MRL will remain as Temporary pending evaluation of data.
Kiwi fruit	2	2	No change to the current MRL and no additional data required.
Mango	*0.05	*0.05	No change to the current MRL and no additional data required.
Milks [in the fat]	T0.2	T0.2	No change to the current MRL and no additional data required.
Oilseed	0.01	T0.01	Existing MRL to be deleted and replaced by Temporary MRL for Oilseed (except cotton seed) while new data are assessed.
Oilseed (except cotton seed)	T0.05	T0.05	Temporary MRL T0.05 established for Codex Commodity classification. Commitment to generate new data has been obtained from registrant.
Passionfruit	*0.05	*0.05	No change to the current MRL and no additional data required.
Pig, Edible offal of	0.1		MRL proposed to be deleted and replaced by appropriate Codex Commodity classification, i.e. Edible offal (mammalian).
Pig meat [in the fat]	0.1		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Edible offal (mammalian) [in the fat].
Pineapple	0.5	T0.5	Existing MRL to be deleted and replaced by Temporary MRL while data is being generated.
Pome fruits	0.2	T0.5	Further data to be assessed. Existing MRL to be deleted and replaced by Temporary MRL while new data is assessed.
Poultry, Edible offal of	0.1	T0.1	MRL to remain as temporary pending assessment of new data.
Poultry meat [in the fat]	0.1	T0.1	MRL to remain as temporary pending assessment of new data.
Sheep, Edible offal of	0.1		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. Temporary MRL for Edible offal (mammalian)
Sheep meat [in the fat]	0.1		MRL to be deleted and replaced by appropriate Codex Commodity classification, i.e. meat (mammalian) [in the fat].
Sorghum	3	T3	Existing MRL to be deleted and replaced by Temporary MRL while data are being generated.
Stone fruits	1	T1	Existing MRL to be deleted and replaced by Temporary MRL pending assessment of new data.
Strawberry	0.05	0.05	No change to the current MRL and no additional data required.
Sugar cane	0.1	T0.1	Existing MRL to be deleted and replaced by Temporary MRL pending assessment of new data.
Tomato	0.5	T0.5	Existing MRL to be deleted and replaced by Temporary MRL pending assessment of new data.

Commodity	MRL Prior to review	Amended MRL	Comment
Vegetables [except asparagus; brassica, cassava; celery; potato; tomato, sweet potato]	*0.01	0.01	Existing MRL to be deleted and replaced by Temporary MRL. Separation of generic vegetable entry into single commodity entries or group entries expected.
Cotton fodder, dry	30	30	No change to the current MRL and no additional data required.
Cotton meal and hulls	0.05	0.05	No change to the current MRL and no additional data required.

The residue definition for all chlorpyrifos MRLs remains unchanged as "Chlorpyrifos".

7.5 Notes on MRLs and Residue Data Requirements

- Retention of MRLs (temporary use or otherwise) will depend on the provision of relevant and appropriate (preferably Australian) residue data or argument.
- Establishment of a re-entry period for animals entering areas treated with chlorpyrifos for mosquito control (the re-entry period on labels will remain as 24 hours during the interim period while data is being generated).
- Further data requirements for ginger root, and potatoes are not considered in the above table as these data requirements pertain to off-label uses under permit. Persons wishing to support these uses with further data should liaise with the Permits Section of the NRA.
- As indicated in Table 7X, there are specific uses and commodities for which data are available and yet to be assessed or uses for which new data are being generated. This is on the basis of commitments that have already been made by various stakeholders.
- If for whatever reason the studies are not proceeded with or if the assessment of data does not satisfy the NRA, any associated uses that remain unsupported will be deleted from labels.

तार का पता: प्रोटेक्शन

Telegram PROTECTION

टेलीफोन/Telephone :

पत्र सं/No. 20-31/2000-CIR.

भारत सरकार

GOVERNMENT OF INDIA

कृषि मंत्रालय

MINISTRY OF AGRICULTURE

(कृषि एवं सहकारिता विभाग)

(DEPARTMENT OF AGRICULTURE AND CO-OPERATION)

वनस्पति संरक्षण, संगरोध एवं संग्रह निदेशालय,

DIRECTORATE OF PLANT PROTECTION, QUARANTINE & STORAGE

एन एच. 4, फरीदाबाद (हरियाणा)-121001

N.H. IV, FARIDABAD (HARYANA)-121001

दिनांक/Dated 17-01-2001.

To

(As per list enclosed).

Subject: Minutes of the 2nd meeting of the Committee to
review the use of CHLORPYRIFOS in the country- Reg.

Sir,

I am enclosing herewith a copy of the minutes of the 2nd meeting of the Committee to review the use of Chlorpyrifos in the country. The comments, if any, may please be sent to the undersigned within a fortnight.

Yours faithfully,

S. Kulshrestha

(S. KULSHRESTHA)
Joint Director (Med.) &
Member Secretary

Copy for information to:

1. Director (CIL) & P.P.A.
- ✓ 2. Secretary CIB/RC.

S. Kulshrestha

(S. KULSHRESTHA)
Joint Director (Med.)
Member Secretary

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MINUTES OF THE SECOND MEETING OF THE EXPERT COMMITTEE TO REVIEW THE USE OF CHLORIPYRIFOS IN THE COUNTRY HELD ON 8.1.2001 AT 10.30 AM IN THE COMMITTEE ROOM OF NATIONAL CENTRE FOR INTEGRATED PEST MANAGEMENT, LAL BAHADUR SHASHTRI BHAVAN, IARI, NEW DELHI

The second meeting of the Expert Committee to review the use of Chlorpyrifos in the country was held on 8.1.2001 at 10.30 am in the Committee Room of National Centre for Integrated Pest Management, Lal Bahadur Shashtri Bhavan, IARI, New Delhi under the Chairmanship of Dr.R.R.Chaudhary, President, Delhi Society for Promotion for Rational uses of Drugs, National Institute of Immunology, New Delhi. The list of participants is Annexed. All the Members of the Committee except Director, HAFFKINE Institute, Mumbai and Dr.Y.Singh, CBRI, Roorkee attended the meeting. However, the comments received from Dr.Y.Singh were duly considered by the Committee during deliberations. No comments have been received from Director, HAFFKINE Institute, Mumbai. At the outset of the meeting, the Chairman welcomed the participants and after a brief introduction, the Agenda items were taken up for the discussion.

The first agenda item of the meeting was 'Confirmation of the minutes of the first meeting held on 20th December, 2000 at Central Insecticide Laboratory, Faridabad. Since there were no comments from any of the Members of the Committee, the minutes were confirmed. Thereafter, the Committee deliberated the information/data collected on Chloripyrifos on various parameters.

The Committee observed that Chloripyrifos with 94% minimum purity is registered for use in the country. One of the impurities present in the Chlorpyrifos is 0,0,0,0-tetra dithio pyrophosphate (Sulfotep) which is allowed upto maximum of 0.3%. This is the only toxic impurity present in Chlorpyrifos. The Committee also observed that in some of the developed countries with 94% purity, the recommended level of Sulfotep impurity is 0.2% maximum. In view of this, the Committee discussed the possibility of reducing the level of this impurity from 0.3% to 0.2%. The representatives of Pesticide Industry Associations mentioned that usually the manufacturers in India are producing the technical grade pesticide of 98% purity which contains lower levels of Sulfotep than the permitted maximum level of 0.3%. However, they were of the opinion that the matter requires discussion among various Members of the Associations and therefore, the final views of the Industry will be presented in the next meeting of the Committee.

The Committee deliberated in detail the information provided on Chlorpyrifos regarding its global registration status, use recommendations in our country and globally and its toxicity (acute and sub-acute and long term and environmental toxicity). The Committee also considered the reasons for ^{the}ban of home uses and revocation of lowering down the tolerance by USEPA in tomato, grapes and apples and noted that the ban in USEPA is a part of an ongoing effort to implement the food Quality Protection Act of 1996 which requires a systematic Government review to all pesticides to ensure that they

meet tighter standards with the goal of protecting children foremost and thus the safety factor has been increased by 100 folds. The Committee also considered the recommendation of National Registration Authority on Chlorpyrifos by Australia. The Committee also considered the minutes of the Advisory Committee on Pesticides, UK in its 277th and 278th meeting regarding Chlorpyrifos and the toxicological evaluation for Pesticides residues in Food carried out by WHO for Chlorpyrifos under the International Programme on Chemical Safety. The Committee also noted that the use of Chlorpyrifos on tomatoes is not approved in India. Based on the toxicological evaluation, the WHO has recommended an ADI of 0.01 mg/kg body weight. Considering these facts, the Committee felt that the existing uses of Chlorpyrifos as approved by the Registration Committee may be continued for controlling insect pests in agriculture. Further, the Committee was of the opinion that Good Agricultural Practices are required to be observed, specially during its use on fruits and vegetables so that the residues do not exceed the maximum limit.

The Committee considered the data/information and various studies available with reference to use of Chlorpyrifos as a termicide in pre and post-constructions of buildings. The Committee noted that as per rough estimates available with the Pesticide Industry, the share of consumption of Chlorpyrifos as a termicide in building is about 8% in India whereas in USA, it is about 52 percent (which also includes other home uses). The Committee also noted that there are no specific studies regarding the impact of Chlorpyrifos treatment for termite for post-construction use on inhabitants of different age group. Therefore, such studies are required to be undertaken under Indian condition within a period of one year. However, the Committee felt that in the absence of any specific adverse affect reported in India the anti-termite use of Chlorpyrifos in buildings may be continued. The Committee also noted that USEPA has restricted /limited the use of Chlorpyrifos at 0.5% solution for its use as termicide, therefore, requested the representatives of Industry to provide reasons for such limitation/restriction.

The Committee noted that all home use of Chlorpyrifos have been cancelled by USEPA from December, 2000, the Committee also noted that National Registration Authority, Australia in its review of Chlorpyrifos in September, 2000 has not supported use of products that contain more than 50 gm./ltr. of Chlorpyrifos by the house-holders due to the toxicity of such products and the need for personal protective equipment, when using such products. In view of the above, the representative of ICPA and IPCA were requested to provide information regarding various formulations registered globally for home uses and the reason for restricting the concentration of 50 gm./ltr. by National Registration Authority, Australia and details of relevant study, if any on the basis of which concentration has been recommended for limiting to 50 gm./ltr. by National Authority of Australia.

The Committee decided to deliberate the home use of Chlorpyrifos in the next meeting of the Committee.

The meeting ended with Vote of thanks to the Chair.

REVIEW OF CHLORPYRIPHOS FOR ITS CONTINUED USE OR OTHERWISE IN THE COUNTRY - RESPONSE FROM DEPTT. OF AGRICULTURE OF STATES/UTs AND SAUs

DEPTT. OF AGRICULTURE OF STATES/UTs & SAUs

RESPONSE

1. Deptt. of Entomology
College of Agri., Dapoli

The use of Insecticide by this University for control of rice pests i.e. gallmidge, stem borer and BPH. It is recommended as a sealing root dip treatment. Apart Chlorpyrifos, the other Insecticides like Chlorfenvinphos, and Isufenphos are also recommended as an alternative. The use of Chlorpyrifos is very limited area.

2. Deptt. of Entomology AHU
Jorhat (M.N. Borthakur)
(Prof. & Head)

It is highly effective against the rice crop pest complex. In root dip treatment (dipped 3 hrs) with 0.02% solution alongwith 1% urea no detable residue observed in rice grain, straw and busk.

Crop - 0.5 kg ai/ha - 0.017 ppm residue

rice 1.0 kg ai/ha - 0.043 ppm residue

Toxicity to Honey bees and Bio control agents. It is highly toxic and residue of toxicity persisted upto 3 days after application

3. Director
CPPS
(Dr. Sabitha Derai-samy)

Residue (Two rounds of application)

Rice @ 500 and 1000 g ai/ha MRL 2 ug/g

Straw - 0.155 - 0.217 ug/g

Grain - 0.079 - 0.136 ug/g Two

Husk - 0.122 - 0.202 ug/g Season

Bran - 0.114 - 0.170 ug/g trails

(four round of @ 800 and 1000 g ai/ha application)

Crop-Cotton

Lint - 0.0454 - 0.0630 ug/g : Two season

Seed - 0.0142 - 0.0694 ug/g : trials

Rice (harvest time) -below detectable

Farm gate samples of Bhindi, Cauliflower, Chillies, tomato, potato, grapes, mango, banana, guava, pomegranate and cardamom were monitored for the residues of Chlorpyrifos.

Only two samples each in Bhindi and Cauliflower one sample each in tomato and chillies were found to be contaminated with Chlorpyrifos residues.

The waiting period suggested by University for Cabbage and beet root - 9 and 7 days respectively.

They initiated the work on monitoring of Chlorpyrifos residues in other commodities viz. milk, feed and bodeer, water and soild samples as the level of Chlorpyrifos was reported to be in high level in Jabalpur water samples.

4. G.B. Pant
University of Agri. &
technology,
Pantnagar.
(Dr. Rameshwar Singh)

The Chlorpyrifos is very useful molecule which is very effective against insects soil, as seed treatment for the control of white grubs, cutworm, termite, and other soil dwelling insects.

At present there is no molecule which can be used as termiticide, even the endosulfan which is also a persistant Insecticide is not a good termiticide.

Chlorpyrifos is also being used for the treatment of the building and also several field, fruit and veg. crops though with the care and sufficient waiting period.

The use of this molecule should be continued till a better/superior molecule is searched available to the farmers.

5. Rajendra Agri University,
Bihar, Pusa, Samastipur
(Dr. A.K. Srivastava)
Director Research

Chlorpyrifos has been studied intensively in this University in vegetables, cereals, Pulses and fruits also. The results of the experiments conducted in the past is very encouraging and found to be most effective in comparison to other Insecticides. The efficacy of the Insecticide is very good. Dose @ 0.05% residues was found to be below detectable level 10 days after application.

6. Dte. of Agriculture,
Thiruvananthapuram

The use of Chlorpyrifos for seed treatment in paddy crop is not much useful.

For bulk quantity also it is not useful.

7. Deptt. of agrichemicals,
B.C.K.U Mohanpur
(Dr. Anjan Bhattacharya)
- Residue:-
1. Crop-Paddy (grain & Straw) Residue well below the MRL value.
 2. No residue was found in cropped soil.
- Views:-
8. Director of Agriculture,
Haryana, Krishi Bhawan,
Sector-21, Panchkula
1. Plant Metabolism study may undertaken.
 2. Effect on non target organitims may studied.
- That Chlorpyriphos is used as a substitute for Aldrin to contains termites in fi Crops. It is also recommended for sp. against many pests.
9. Dte. of Agriculture,
Mizoram, Aizawal
- We are not experiencing any adverse eff. of Chlorpyriphos.
10. Deptt. of Entomology,
CCS, HAU, Hisar
- Chlorpyriphos is an effective alternat to aldrin, Endosulfan, Lindane for term control as seed treatment, and vari insects/pests of crops. It is a effective as soil application. Liberal of this insecticide should be discourag
11. Deptt. of Entomology,
Punjab Agri. University,
Ludhiana
- Recommended use of Chlorpyriphos did leave any detectable resudues.
12. H.P.K.U.
Deptt. of Entomology
Palampur
(Dr. N.P. Kashyap)
- Himachal Pradesh farmers are us Chlorpyriphos as soil treatment and insec pests. Recommended for continued use.
13. Deptt. of Entomology,
J.N.K.V.U, Japalpur
(Dr. S.M. Vaishampayan)
- Very good result against Caterpillar/Pe Insects. Excellent substitutes of DDT BHC No significant residue Probl Strongly use for continued use.
14. Director of Research
U.A.S, Dharwad
- Effective use various Insect/Pests Cotton, Paddy Sugarcane, Pomegranate well as soil application for term control



ANNEXURE - 2/50 -

102 Creative Industrial Building,
Sundernagar, Road No. 2, Kalina,
Santacruz (E), Mumbai-400 098.

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Total No. of pages - 6

February 20, 2001

Dr (Mrs.) S. Kulshreshta
Joint Director (Medical) & Member Secretary,
Review Committee on chlorpyrifos
Ministry of Agriculture
Department of Agriculture and Co-operation
N.H.-IV,
Faridabad -121 001

Dear Madam,

During the 2nd meeting of chlorpyrifos review committee, the Associations of pesticide industry were asked to provide information/views on some of the following points: -

1. Views on the possibility of reducing the maximum sulfotep content from 0.3 to 0.2 % in the manufacture of chlorpyrifos.
2. Possible reasons for reducing the concentration of chlorpyrifos from 1.0% to 0.5 % for termite control in USA.
3. Formulations of chlorpyrifos registered globally for home usage
4. The reason for restricting chlorpyrifos formulation having in excess of 5 % a.i for home garden and domestic pest control in Australia
5. Studies on impact of chlorpyrifos treatment for termite control in post construction use on inhabitants of various age groups.

Our ICPA had a meeting to discuss on above points. Based on the outcome of this meeting and also the information obtained from some of the countries, general consensus was arrived at our Association members and the views of ICPA are given below.

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1) Views on the possibility of reducing the maximum sulfotep content from 0.3 to 0.2 % in the manufacture of Chlorpyrifos.

The level of 0.2 % maximum sulfotep cannot be routinely achieved even with the best manufacturing processes and could be only met by selection of suitable batches from the large batches processed annually. This level cannot be routinely met at the production plants in India without incurring considerable extra costs. The toxic waste thus, produced will be difficult to legitimately dispose off.

By reducing the sulfotep level from 0.3 % to 0.2 % is not likely to further reduce the already known hazard level, to any perceivable extent.

It is pertinent to mention that, the permissible level of sulfotep in USA is 0.6 %.

The criteria for reducing the sulfotep level to 0.2 % in Australia is borne by the fact that some formulations of chlorpyrifos are used on pets for controlling insect pests. Earlier, in Australia certain formulations of diazinon which also has sulfotep as impurity when used on pets were reported to cause hazards and, one of the possible reason attributed was the presence of this impurity. Though, this has not been scientifically proved to avoid possible risks when used on pests, the level of sulfotep was also kept at 0.2 % in Chlorpyrifos.

However, in our country chlorpyrifos formulations are not registered for use on pets. Therefore, in view of the position explained above, ICPA feels that the present level of 0.3 % of sulfotep in chlorpyrifos be retained.

2) Possible reasons for reducing the concentration of chlorpyrifos from 1.0% to 0.5 % for termite control in USA.

The reason for reducing the concentration for termite control in the USA was to lower the theoretical exposure to workers applying the product. In modeling calculations of worker exposure the total dose absorbed into the body is directly proportional to the concentration of active ingredient in the formulation. Since, according to the new FQPA law and the associated Acceptable daily intake (ADI), worker exposure was considered to be excessive, a lowering of the applied concentration of chlorpyrifos could reduce the theoretical exposure to within allowable levels.

In principal, this Committee has agreed to follow FAO/WHO ADI/MRL values in our country and therefore, by reducing the concentration of chlorpyrifos from 1.0 to 0.5 % for termite control will not make any practical change.

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Hence, the present level of approved formulations be permitted for use which depends upon the conditions of usage, the intensity of termite infestation and the species of termite required to be controlled.

3) Formulations of chlorpyrifos registered globally for home usage

As per the information readily available with Dow AgroSciences, the formulations of chlorpyrifos with less than 5 % a.i approved for home usage in various countries is given in the enclosed list.

It is pertinent to mention that, there are many other formulations of Dow AgroSciences and other companies manufacturing chlorpyrifos having more than 5 % a.i in them and are approved for home usage in different parts of the world.

4) The reason for restricting chlorpyrifos formulation having in excess of 5 % a.i for home garden and domestic pest control in Australia

The NRA guidelines "Guidelines for pesticides used by householders, Ag requirements Series. Part 3, Toxicology, Appendix 3-1" indicate that pesticides for household, home garden or domestic use should be relatively harmless or capable of causing only mild illness, if poisoning occurs. They should not cause any irreversible toxicity on repeated exposure, nor require the safety/personal protective equipment that is not readily available to householders. The authorities felt that in dilute form chlorpyrifos was safe to be used by amateurs and sold in over-the counter products.

5) Studies on impact of chlorpyrifos treatment for termite control in post construction use on inhabitants of different age groups.

Following two studies have already been conducted in India on above aspect.

- The post spraying effect of 2% chlorpyrifos on inhabitants of houses have been studied as per the approved protocol by the Registration Committee. The volunteers (adult males, females and children) did not show any remarkable changes as shown by the clinical examination and laboratory investigations of blood samples for various hematological and biochemical parameters.

Thus, home usage of chlorpyrifos did not cause health hazard to human volunteers, sprayers and inhabitants of various age groups.

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Continuation Sheet

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- Investigations with chlorpyrifos 50 % EC when used as post construction termiticide and, its effect on spray operators, as per the approved protocol by Registration Committee, has been conducted. The findings indicated no clinical signs of toxicity, no changes in hematological, biochemical and urinalysis parameters. Thus, there was no adverse effect of chlorpyrifos on spray operators who undertook post construction termite control operations.

In view of the outcome from the reviews made on chlorpyrifos usage and its associated risk on people of various group and also, the specific studies conducted in our country as briefly indicated above, our Association is of the opinion that no additional and useful purpose would be served by taking up studies on post construction use of chlorpyrifos and its effect on people of different age group.

We request you to keep above factual position in to consideration during the next meeting for taking appropriate decisions.

Thanking you and assuring you of our best cooperation.

Yours truly,



Dr. A. S. Indulkar
Executive Director

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**Information regarding various formulations of Chlorpyrifos
registered Globally for Home uses**

PRODUCTS OF CHLORPYRIFOS (WITH LESS THAN 5% OF A.I) USED FOR PEST CONTROL OPERATIONS IN VARIOUS COUNTRIES

COUNTRY	CONCENTRATION	PRODUCT NAME	Type	USES
ALGERIA	0.04	EMPIRE MAISON	CS	Indoor Pest Control
AUSTRIA	15 g/kg	CORTILAN SP.	RB	Pest Control Operations
CANADA	0.5%	DURSBAN WB05		Indoor Pest Control
CLISS	50 g/L	DURSBAN 5% INDUSTRIAL DUST	DP	Non Crop
FRANCE	0.6%	QUINO BLANC D438		Pest Control Operations
FRENCH POLYNESIA	0.6 %w/w	SWAT GEL	PC	Indoor Pest Control
GERMANY	1%	AMEISENMITTEL-N-DOWELANCO		Pest Control Operations
GERMANY	1%, 3%	DETMOL-LEX		Pest Control Operations
GERMANY	0.6%	SWAT GEL.	RB	Indoor Pest Control
ITALY	0.4%(4g/l)	DURSBAN PRO	AL	Pest Control Operations
ITALY	0.4%(4g/l)	ENFORCER RTU	AL	Pest Control Operations
ITALY	240 g/l	GETT	EC	Pest Control Operations
ITALY	0.4%(4g/l)	INSETTICIDA PRONTO	AL	Pest Control Operations
KENYA	4	EMPIRE 0.4 % RTU		Indoor Pest Control
MADAGASCAR	50	GLADIATOR 4TC	DP	Non Crop
NETHERLANDS	4 g/L	GETT	CS	Indoor Pest Control
NEW CALEDONIA	0.6 %w/w	SWAT GEL	PC	Indoor Pest Control
PARAGUAY	25 g/Kg	DURSBAN 2.5P	DP	Ant Control
POLAND	0.4%	GETT	CS	Pest Control Operations

-:2:-

3. **NRA, Australia decision to restrict the concentration of Chlorpyrifos to 50 g/l for home uses :**

The type of use for which the Chlorpyrifos concentration has been restricted to 50 g/l by NRA, Australia is not relevant since in India such uses are not approved.

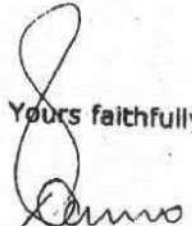
4. **Studies on Impact of Chlorpyrifos treatment for termite control (post construction) on inhabitants of various age group in Indian conditions**

We believe that some Indian as well as International data are available on air concentration of Chlorpyrifos following post construction termiticidal use. The approved method of use does not leave detectable concentration of Chlorpyrifos in air beyond few hours. Hence, the proposed study might not add to the existing knowledge.

You are requested to keep our views in mind while preparing the Agenda for the 3rd Meeting.

Thanking you,

Yours faithfully,


(Gen. Ravi Varma)
Executive Director

Cc : Mr. R.D. Shroff
Chairman - PAI, UPL For information

CC : Dr. R.S. Banerjee For information
Gharda Chemicals Ltd.
International Marketing & Development Dept.
B-27, MIDC
Dombivili (E) - 421 203
DIST THANE, MAHARASHTRA

160-156

ANNEXURE - 3

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PESTICIDES ASSOCIATION OF INDIA

1202, NEW DELHI HOUSE, 27 BARAKHAMBA ROAD, NEW DELHI - 110 001

PLEASE QUOTE
IR:2001

19th February, 2001

Mr. S. Kulshrestha
 Joint Director (Med.)
 Ministry of Agriculture
 Dept. of Agriculture and Co-operation
 Directorate of Plant Protection
 Quarantine Storage
N.H. IV, FARIDABAD -121 001 (HARYANA)

Sub: Meeting to review the use of Chlorpyrifos in the Country

Dear Sir,

Reference your letter No. 20-31/2000-CIR-II dated 18-12-2000.

As you are aware the Second Meeting of the Experts Committee was held on 8th January, 2001 in the Committee Room in NCIPM, IARI, New Delhi. Minutes of the same have been received by our representative. Our view on the subject are as follows :-

1. **Possibility of reducing Sulfotep from 0.3% to 0.2%**
 We understand the level of Sulfotep in Chlorpyrifos is not the issue of concern in various countries where Chlorpyrifos is registered and being reviews. Various countries have permitted varying levels of Sulfotep in Chlorpyrifos Technical (from 0.6% in USA to 0.2% in Australia). Further, we understand that FAO is currently finalizing the specification of Chlorpyrifos (the specification on Chlorpyrifos is likely to be finalized by end 2001) where the Sulfotep level will get addressed. Lastly, we believe that Sulfotep either at 0.3% level or 0.2% level is unlikely to alter/influence the overall toxicological profile of Chlorpyrifos significantly.
2. **US EPA restriction on Chlorpyrifos as 0.5% solution for its use as termiticide :**
 We believe that this decision of US EPA is for the purpose of complying the FQPA requirement rather than on scientific logic.

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ANNEXURE 4(A)

EXTRACTS FROM THE AGENDA OF 2025 R.C.
MEETING
Agenda
Item No. 3.3

- 161 -

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Ban on use of pesticide Chlorpyrifos
Govt. (Environmental Protection Agency)

The US Govt. (Environmental Protection Agency) has banned the most widely used pesticide ^{Chlorpyrifos} in US households on 8th June, 2000 as it could be harmful to children. The news reports appeared in various newspapers in this regard which have been sent to Plant Protection Adviser to the Government of India for comments/examination are at Annexure A-1 and A-2 respectively. In India, under the Insecticides Act, 1968, the use of Chlorpyrifos is approved on agricultural crops and as a termiticide in pre and post construction of buildings. A copy of note sent to DAC on the subject matter by the Plant Protection Adviser to the Government of India indicating the current status of Chlorpyrifos registration/use and the points which requires consideration may be perused at Annexure-B.

Members may like to deliberate and decide further course of action for processing of pending applications of Chlorpyrifos formulations for use in household.

761 (P)
14/6

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दिनांक Dated 15/6

1805/JS (PP) / 2000

16/6

Dy. No. 1673 / AS (NY)
Date: 14.6.2000

US Govt bans use of pesticide Dursban

Reuters

WASHINGTON, June 9

THE federal government on Thursday banned most home uses of the pesticide Dursban — the most widely used pesticide in the nation found in some 20 million homes — due to neurological health risks including blurred vision and memory loss.

The ban is part of an ongoing effort to implement the Food Quality Protection Act of 1996, which requires a systematic government review of all pesticides to ensure they meet tighter standards with the goal of protecting children foremost.

The EPA Administrator, Ms. Carol Browner, said the action followed a scientific review which showed health risks to children, who are more likely to come into

contact with the pesticides at homes and schools, and by eating foods like grapes and apples.

"In terms of how best to go about protecting our children, this was the fastest possible way for us to get the kind of (swift) reduction in the manufacturing of Dursban, Ms. Browner told reporters. "We are getting a 10-million-pound reduction in the manufacturing of this pesticide by the end of this year." EPA said blurred vision, muscle weakness, headaches and memory loss have been linked to exposure to large amounts of Dursban, leading to the restrictions announced on Thursday.

Ms. Browner said new, safer alternatives can replace Dursban.

Dursban is the popular trade name for a pesticide which has been used for three decades in households across the country.

Insecticide caution

Automatic insecticide dispensers used to control flying insects in restaurants, schools and hospitals could pose a public health risk if improperly installed, US officials said on Thursday.

The Atlanta-based Centres for Disease Control and Prevention (CDC), in what it said was the first report to document pesticide-related illnesses from aerosol dispensers, said the devices had made 97 people sick since 1986.

CDC researchers said people became ill from the pyrethrin or resmethrin pesticides used in the dispensers, which typically spray a fine mist of insecticide every 15 minutes around the clock.

Ailments generally involved eye, nose or throat irritation and, at times, respiratory, gastrointestinal, or neurological systems.

APRA/2K
19/6/2000
CCB/2K
20/6/2K

Handwritten notes and signatures

Most Immediate
Rob
19/6
Secretary
DFA

16/6
J.S. (PP) - on Tour
16/6