REGULATORY REVIEW DECISION FOR THIACLOPRID

AND ITS ASSOCIATED END-USE PRODUCTS

Contacts: The Chief Executive Officer/Secretary Pest Control Products Board: P.O Box 13794 – 00800 Loresho, Nairobi Kenya: Website: https://www.pcpb.go.ke/ email: info@pcpb.go.ke | md@pcpb.go.ke |Tel: +254 720 480 904

Table of Contents

Contents

1.0 Introduction *3*

2.0 Main objectives of the review *3*

3.0 Uses of Thiacloprid *3*

3.1 Mode of action of Thiachloprid **3**

3.2 Registered uses of Thiachloprid in Kenya **3**

4.0. Data considered in the review *4*

5.0 Methodology *4*

6.0 Outcome of the Review *5*

6.1: Potential for carcinogenicity to humans **5**

6.2: Potential for Genotoxic effects **5**

6.3: Potential for Reproductive toxicity **5**

6.4: Hazard assessment **5**

6.5: Dietary risk assessment **6**

6.6: Effects on non-target organisms **6**

6.7: Fate and behaviour in soil and water **6**

6.8: Incident reports **6**

7.0 Proposed review decision for Thiacloprid *7*

7.1 Next steps **8**

8.0 References *9*

APPENDIXES *10*

Appendix I: Summary of international regulatory decisions **10**

Appendix II: Public comments on Thiacloprid and end use products **12**

Appendix III: Registered pest control products containing Thiacloprid - (Not in the text) **15**

1.0 Introduction

Following initial authorization on use of pest control products, regulatory authorities all over the world may review the status of authorization routinely or when new information becomes available that the pest control product has safety concerns. The process of review must be based on the existing laws and regulations.

Pursuant to Regulation 11(2b) of the Pest Control Products (Registration) Regulations of 1984 of the Pest Control Products Act (PCPA), the Pest Control Products Board (PCPB) initiated a review of Thiacloprid and Thiacloprid based end use products based on new information that Thiachloprid may present risks for fertility and prenatal development (may damage the unborn child) . The product was also said to be highly toxic to bees.

2.0 Main objectives of the review

I. Review existing scientific data in view of establishing the weight of evidence if any that supports the safety concerns.

II. Make recommendations for consideration by the board.

3.0 Uses of Thiacloprid

3.1 Mode of action of Thiachloprid

Thiacloprid is a chloronicotinyl insecticide which acts as an agonist of nicotinergic acetylcholine receptors (nAChR) and it is therefore effective against insects resistant to acetylcholinesterase inhibitors. It acts by disruption of the insect's nervous system by stimulating nicotinic acetylcholine receptors leading to disorder of the nervous system hence the death of the pest.

3.2 Registered uses of Thiachloprid in Kenya

In Kenya Thiacloprid is registered for use as an insecticide for the control of thrips, aphids, whiteflies, spider mites, mealybugs and caterpillars on Roses; thrips in carnations; thrips and whiteflies in tomatoes; and thrips in Onions. There are three (3) products approved in Kenya (Appendix III) as of 26th November 2021.

4.0. Data considered in the review

Currently available relevant scientific information, data submitted by the applicants to support approval of the individual products in Kenya, initial information provided by stakeholders various regulatory decisions made around the world including FAO/WHO Joint Meeting on Pesticide Residues, the European Union, the United States Environmental Protection Agency, Health Canada, Australia Pesticide and Veterinary Medicine Authority
.
A summary of the regulatory decisions is presented in Appendix I. While appendix II represents information collected from stakeholders

5.0 Methodology

In compliance with the constitution of Kenya on the bill of rights, and public participation, the board wrote a circular to the local agents and the public notifying them of the intended review and called for any information that would assist the reviewers in arriving at the correct decision. The feedback was to be received within 90 days from the date of notification.
This was followed by a call for experts from Government institutions that included the Universities, Toxicological society of Kenya, KALRO, and KePHIS etc. After evaluation of the applications, four external experts were selected to team up with experts from PCPB. Four active ingredients were reviewed and reports made and later submitted to the board of management. The board recommended that the outcome of the review be subjected to a second round of public participation.

6.0 Outcome of the Review

6.1: Potential for carcinogenicity to humans

Following long-term exposure in rats, in addition to the liver, effects were observed in the thyroid, eye, nervous system and muscles whereas in mice effects were observed in the adrenals, lymph nodes and ovaries in addition to the liver.

Neoplasia were observed in both rats (uterine adenocarcinomas and thyroid follicular cell adenomas) and mice (benign ovarian luteomas). Increased thyroid and uterine tumours in rats and ovarian tumours in mice and rats Classified as "Likely human carcinogen". The rats, mice and dog sub chronic studies evaluated the liver as the target organ. The review noted that further studies/verification was needed before reproductive effects could be correlated with increases in enzymes (potential for secondary effects on reproductive organs (testes, ovaries and uterus)

6.2: Potential for Genotoxic effects

From the evaluation of negative in vitro and in vivo genotoxicity studies, Thiacloprid is unlikely to be genotoxic. A definite mode of action for the tumour formation was not demonstrated but uterine and ovarian tumours may have resulted from an endocrine-mediated activity; thyroid tumours were likely a consequence of liver enzyme induction, but human relevance of these tumours could also not be excluded.

6.3: Potential for Reproductive toxicity

At maternally toxic doses (MTD) increased stillbirth, dystocia (difficulty giving birth), decreased live births, decreased pup viability and pup weights were observed; developmental effects noted at MTD increased resorptions, skeletal retardations, and variations, decreased foetal weights.

6.4: Hazard assessment

The specifications of Thiacloprid are ≥975g/kg for FAO 2010 and EFSA 2019 while for Australia the specification is ≥985g/kg . The relevant impurities Methanol and Dimethylsulphate (DMS) have not been declared in the FAO and Australia specification. The EFSA specification has declared methanol at 0.63g/kg. The declared purity profile of

DOBERMAN 15% OD and TRUENCER 480 SC is 97.9%w/w while that of CALYPSO SC is 96.7 w/w with no impurities of toxicological concern for the three products. The purity profile of Calypso SC was below the FAO and EFSA Specifications.

6.5: Dietary risk assessment

Residue data from supervised residue trials submitted for Calypso SC 480 on Tomato, Chilies, Eggplant and Karella and Doberman 15% OD on Onions was evaluated. The data was considered adequate to support the registered Kenyan GAP in these crops.

The result of the FAO IEDI (International Estimated Dietary Intake) calculations indicates that there is no unacceptable acute or chronic risk to the common health from the consumption of tomato, pepper, eggplant, onions and karella (bitter melon) treated with Thiacloprid according to the representative intended use.

6.6: Effects on non-target organisms

Thiacloprid is highly toxic to bees.

6.7: Fate and behaviour in soil and water

In soil laboratory incubations under aerobic conditions in the dark, Thiacloprid exhibited very low to low persistence. Thiacloprid exhibited medium to low mobility in soil. In laboratory incubations in dark aerobic natural sediment water systems, Thiacloprid exhibited moderate persistence.

6.8: Incident reports

As of 30th October 2022, there were no incidents relating to the human health or environmental aspects of concern reported.

7.0 Proposed review decision for Thiacloprid

Pursuant to Regulation 11(2b)[1] of the Pest Control Products (Registration) Regulations, 1984 of the Pest Control Products Act, the evaluation of available scientific information related to the aspects of concern indicates that the potential human health and environmental risks could not be concluded.

Review of the registrant dossier (data) showed that the chemistry purity profile of the technical material for Thiacloprid did not provide any impurity of toxicological and ecotoxicological concerns.

Residue data from supervised residue trials submitted for the two products containing Thiacloprid on onion, tomato, chilies, eggplant and karella (bitter melon) was evaluated and results indicated that the current MRLs for these crops will not be exceeded using Kenya GAP (good agricultural practices).

Alternatives: Thiacloprid acts by disruption of the insect's nervous system by stimulating nicotinic acetylcholine receptors leading to disorder of the nervous system hence the death of the treated pest. In Kenya Thiacloprid is registered for use as an insecticide for the control of thrips, aphids, whiteflies, spider mites, mealybugs and caterpillars on Roses; thrips in carnations; thrips and whiteflies in tomatoes; and thrips in Onions. Based on this a number of conventional and biopesticides are registered for use in Kenya for similar uses on the same crops, although some of the alternative products are based on old molecules and are a subject of review.

[1] 11. Suspension and revocation of certificates of registration
(1) The Board may suspend or revoke a certificate of registration issued under these Regulations for such time as the Board may determine.
(2) The powers conferred by paragraph (1) shall not be exercised by the Board except on one or more of the following grounds—

(b) that new information has become available to the Board which renders the pest control product unsafe or dangerous;

7.1 Next steps

It was concluded from the review of the registrant data and literature review from other regulatory agencies, more data is required on toxicological and environmental studies.

8.0 References

The list of pest control products https://www.pcpb.go.ke/on-crops/

https://www.pcpb.go.ke/wpcontent/uploads/2020/10/guidance_on_dossier_evaluation_for_te_registration.pdf

https://www.fao.org/fileadmin/templates/agphome/documents/Pests_Pesticides/JMPR/JMPRrepor2006.pdf (accessed 25th November 2021)

https://efsa.onlinelibrary.wiley.com/doi/full/10.2903/j.efsa.2019.5595 (accessed 25th November 2021)

https://www3.epa.gov/pesticides/chem_search/cleared_reviews/csr_PC-014019_23-Jul-03_a.pdf (accessed 22th November 2021

APPENDIXES

Appendix I: Summary of international regulatory decisions

Country/Region	Regulatory decision	Mitigation measures
European Union	withdrawn	The approval criteria for Thiacloprid according to point 3.6.4 of Annex II of Regulation (EC) No 1107/2009 are not met since the harmonised classification of Thiacloprid includes toxic for reproduction category 1B (Repro. 1B), *unless the exposure of humans to that active substance, under realistic proposed conditions of use is negligible* The available groundwater exposure assessments indicate that for the relevant groundwater metabolites M30, M34 and M46, annual average recharge concentrations moving below 1m depth will be above the parametric drinking water limit of 0.1 lg/L for both the representative uses in all the relevant FOCUS groundwater scenarios
United States of America	Voluntary cancellation by the registrant	Voluntary withdraw by the registrant
Canada	Approved	
JMPR	Evaluated	Codex Maximum residue limit (MRLs) set for: Almond hulls, Berries and other small fruits, Cotton seed, Cucumber, Edible offal (mammalian), Eggplant, Eggs, Kiwifruit, Meat (from mammals other than marine mammals), Melons, except watermelon, Milks, Mustard seed, Peppers, sweet (including pimento or pimiento), Pome fruits (group), Potato, Poultry meat, Poultry, edible offal of, Rape seed, Rice, Squash, summer, Stone fruits (group), Tomato, Tree nuts (group), Watermelon, Wheat, Wheat, hay and/or straw, Winter squash
Australia	approval granted for crop and animal (topical solution)	Withholding period: **Crops**: Apricots cherries nectarines plums: Do not harvest for 14 days after application. Peaches and pome fruit: Do not harvest for 21 days after application. Do not graze any plants that were present in the sprayed area at the time of application. **Sheep**: MEAT: DO NOT USE less than 42 days before slaughter for human consumption. MILK: DO NOT USE on ewes which are producing or may in the future produce milk that may be used or processed for human

Country/Region	Regulatory decision	Mitigation measures
		consumption. WOOL: DO NOT USE less than 6 months before shearing or fibre collection
New Zealand	approval granted	on label of sampled product: Harmful if swallowed. 6.7B Suspected of causing cancer 6.8B Suspected of damaging fertility or the unborn child 6.9B May cause damage to organs through prolonged or repeated exposure 9.1A Very toxic to aquatic life with long lasting effects 9.2C Harmful to the soil environment 9.3B Toxic to terrestrial vertebrates 9.4C Harmful to terrestrial invertebrates.

Appendix II: Public comments on Thiacloprid and end use products

No	Comments	Respondent
1.	a) Our markets requires that we export pest free products which will be difficult to achieve without some of their active ingredients. b) Our resistance management strategies requires that we avoid overreliance of same active ingredients. We need to have a wider selection option to enable us achieve a working pesticide rotation program. c) We are restricted by the markets on the number of chemicals we can spray on our crops, removing these ingredients will live us with very limited choices which may result into pest and disease build up beyond economic threshold hence will have negative impacts on our business	HADITHI PLANTS K LIMITED, FAIRY FLOWERS K LIMITED AND LATHYFLORA K LIMITED
2.	We are writing to request for retention of some very important active ingredients in our crop protection program. We recognize the effects that pesticide have on the ecosystem and need to use them responsibly. However, we are already restricted on most active ingredients that we cannot use on our products by the market. Further, we are also under pressure to export pest and disease free product. Removing some of these products will rely strain our production process which will have great negative impact on our business. We have adopted Crop protection management strategies, which ensure responsible use of pesticides and guarantee minimal negative impact to people and environment.	AFRICALLA KENYA LTD

No	Comments	Respondent
3.	Essential for aphids, thrips & whiteflies which cause havoc on crops.	Kenya Flower Council
4.	We can do without	EQUINOX FLOWERS
5.	For the control of various insect pests, most of the Neonicotinoids, a big chunk of them have been banned due to their effect on the pollinating agent – the bee. Only a few are still left and removing this also shall spell doom for the industry. It is also one of the few NNIs still allowed to be used.	Penta Flowers
6.	No immediate suitable alternatives	Finlays Flowers
7.	use with risk mitigation- risky to wildlife and aquatic organisms	SASINI PLC
8.	a) Increase public capacity building on safe use of pesticide application, create public awareness, PPEs, do more research and allow industry self-regulation. b) Identify and publicize crops which the selected active ingredients have been proved to be harmful to humans, animals and the environment. c) Follow Plant Protection (General) Regulations, 2021 where such incidences of perceived harmful effects of a pesticide are suspected.	Fresh Produce Consortium of Kenya (FPC Kenya)

No	Comments	Respondent
	Active ingredient that must be withdrawn immediately. Proposed withdrawal in Kenya should be based on: • Likelihood of being a carcinogen • High bee toxicity	Biodiversity and Biosafety Association of Kenya (BIBA-K) Kenya Organic Agriculture Network (KOAN) Resources Oriented Development Initiatives (RODI) Route to Food Initiative (RTFI)

Appendix III: Registered pest control products containing Thiacloprid - (Not in the text)

	Trade name of the product and registration number	Active ingredient	Registered uses
1.	CALYPSO SC 480 Suspension Concentrate PCPB(CR)0291	Thiacloprid 480g/L	Insecticide for the control of Aphids, Whiteflies on Roses; Thrips on Carnations; Aphids, Thrips & Whiteflies on Tomato, Chilies, Eggplant & Karella.
2.	DOBERMAN 15% OD PCPB(CR)1528	Thiacloprid 130g/L+ Deltamethrin 20 g/L	Insecticide for control of Mealybugs, Thrips, Caterpillars, Spider mites and whiteflies on Roses, thrips in onions
3.	TRUENCER 480 SC PCPB(CR)1550	Thiacloprid 480g/L	Insecticide for control of aphids, whiteflies and thrips on Roses