PSGR
Physicians & Scientists for Global Responsibility

Email: info@PSGR.org.nz
Social: @PSGRNZ
Website: PSGR.org.nz

December 4, 2024.

PSGR welcome the opportunity to send in a response to NZEPA's proposal to ban chlorpyrifos APP204694.[1 2 3 4] Thirty years of epidemiological and laboratory research has produced a weight-of-evidence that demonstrates that chlorpyrifos is a developmental neurotoxicant.

NZEPA has an obligation to risk to human and environmental health (domestic), and risk to trade (export).

The U.S. Environmental Protection Agency (USEPA)[5 6] and the European Food Safety Authority (EFSA) determined that the insecticide CPY and CPY-M inhibit the enzyme acetylcholinesterase (AChE). EFSA revoked approvals for the insecticide chlorpyrifos[7] and common cereal grain storage fumigant, chlorpyrifos-methyl.[8] The maximum residue level (MRL) for CPY and CPY-M in Europe is 0.01 mg/kg, the lowest level that can be measured by analytical laboratories.[9]

EFSA revoked authorisations based on uncertainty relating to CYP and CYP-M's genotoxic potential and the evidence of brain alterations, noting that the recorded toxicological effects meet the criteria for classification as toxic for reproduction category 1B (regarding developmental toxicity). For example (2019a, page 8):

> It is well known that morphometry of brain regions is a valuable data for regulatory authorities (Tsuji and Crofton, 2012): the decrease in cerebellum height corrected by brain weight was considered an adverse effect indicating a damage of the architecture of the developing brain (in 2014, the PPR Panel considered the relevance of morphometric analyses as endpoint for hazard characterisation 4).The structural changes in the developing rat brain found in regulatory studies are consistent with human data. In particular, children with high prenatal exposure to chlorpyrifos showed frontal and parietal cortical thinning (Rauh et al., 2012).

AChE, binds to the neurotransmitter acetylcholine (ACh), mediating levels in the body and brain to prevent bioaccumulation of acetylcholine, a neurotransmitter that is involved in memory, learning, attention and muscle movement. The role as a neurotransmitter in the autonomic nervous system is particularly important. Prenatal, early postnatal, and adolescent brain maturation is physiologically regulated by acetylcholine (ACh).

The conclusion of regulatory agencies that AChE activity was inhibited in erythrocytes (red blood cells) which are throughout the body, was an important step in the process of recognising the risk from CPY and CPY-M. It was not just the brain that was at risk.

FOOD CONTAMINATION AND TRADE RISK

High residue levels in meat and animal and dairy fat is derived from feed that has been treated with CPY and CPY-M.[10] In New Zealand this may be either domestically grown feed, or imported feed, predominantly from Australia. As an exporter of meat and dairy products into Europe (with MRLs at 0.01 mg/kg), and other countries that have restricted CPY and CPY-M, New Zealand must recognise that there is a trade-related risk, if CPY and CPY-M contaminated feed is fed to livestock.

A second trade-related risk comes from food exporters who use food ingredients from Australia, who may be unaware that Australian tolerances for CPY and CPY-M are orders of magnitude higher than European limits.

In September 2024, the Australian Pesticides and Veterinary Medicines Authority (APVMA) removed 79 of 91 agricultural and urban pest control uses of chlorpyrifos, citing trade-related concerns.[11] Australia has retained approval for Cole (brassica) crops (broccoli, brussels sprouts, cabbage, cauliflower), Clover seed crops, Forage crops, Lucerne, Lucerne seed crops, Medics, Agricultural, commercial and industrial areas (not publicly accessible), Container plants in soil or other growing media (commercial), Hides/skins, Potted ornamentals (commercial), Treatment of termite nest or colony (in wall cavities), Turf (commercial).[12]

Australian maximum residue levels for brassica crops are .05 mg/kg. Australia will permit CPY to be sprayed to a wide range of animal forage crops. Therefore, milk fat levels of CPY can be as high as 0.2 mg/kg and CPY-M 0.5 mg/kg, and meat fat CPY and CPY-M levels can be as high as 0.5 mg/kg. Cereal grain levels for CPY remain at 0.1 mg/kg. The highest levels are from grain storage fumigant CPY-M on cereal grains 10 mg/kg, lupins 10 mg/kg, wheat bran 20 mg/kg and wheat germ 30 mg/kg.[13]

Australia has kept its high MRLs for brassica crops. Vegetable growers in New Zealand have successfully grown brassica crops for the domestic market for a decade. One treatment, ozone, acts as a fumigant and suppresses insect populations at the first, second and third stages of the insects' lifecycle. Due to negligible toxicity due to rapid dispersal in air, there are no with-holding periods, and windy days are not a problem.

As New Zealand's north island is a large consumer of Australian-grown products, they will be exposed to these high residue levels. However, for value-added food-based industries, the high MRL levels, if the product is used as an ingredient in potential export product, will be a trade risk.

HUMAN HEALTH RISK

It is perplexing that worker re-entry risk for pre-conception and pregnant women has not been reviewed when the primary risk identified globally is to pregnant women, the foetus and young children. NZEPA's dismissive and simplistic discussion on developmental neurotoxic risk suggests that officials may not have the skill-set for this work, but also results in misleading information being communicated to the public.

PSGR's Report which is supplementary to this comments paper shows that the NZEPA has stepped away from formal risk assessment, and cannot claim that assessments in 2012-2013 and 2024 reflect a level of rigor required for risk assessment.

> 'Children (from the prenatal period through adolescence) often react differently to chemicals than do adults because, compared to adults, they have different exposures, different vulnerabilities determined by critical windows of development, and a longer life ahead of them. "To protect children's environmental health (especially for the foetus and the small child), it is important to understand when and how they can be particularly vulnerable to chemical exposures. Understanding the rapidly changing nature of the child is essential to understanding vulnerability to chemicals" (IFCS 2003).'[14]

The NZEPA have not considered that New Zealand children have higher exposures of the common metabolite of chlorpyrifos, chlorpyrifos-methyl and triclopyr than children in the U.S., Spain, or Thailand.[15] The NZEPA could have investigated the findings from this 2022 New Zealand study, but have not. There is no known level of exposure that is safe for pregnant women and the developing foetus.

> 'One US study found that as little as 4.6 parts per trillion of chlorpyrifos in umbilical cord blood during gestation was associated with a drop of 1.4 percent in a child's IQ, and 2.8 percent of its working memory.'[16] [17]

Developmental delays are a problem in New Zealand infants and children. One-in-four New Zealand children were recently classified as having suboptimal developmental health[18] and special education needs has substantially grown over time.[19]

Despite having large agrarian communities across New Zealand, and females who play golf and could be pregnant (turf) the key risk exposures in pregnancy or in early life has been completely ignored in modelling scenarios for acute or re-entry risk and the problem of persistence and repeated exposures in workplaces (including agricultural settings). One dermal absorption study on time-pregnant Fischer 344 female rats is not good enough. The APVMA also failed to conduct any analysis of risk to pregnant women.

As Dr Meriel Watts discussed in the book

> 'One study, which quantified exposure estimates for a population of young farmworker children in the USA, found that 95% of 115,000 different exposure scenarios and dose estimates posed a risk to children's health from chlorpyrifos exposure (Beamer et al 2012).'

Watts drew attention to ambient exposures:

> 'not just those rural children living on farms or near fields that are affected: ambient community (i.e. away from the fields) air monitoring data from agricultural regions of California showed that short-term chlorpyrifos exposure estimates exceeded the 'acute reference dose' (another way of saying an 'acceptable dose') for 50% of children; and non-cancer risks were higher for children than adults (Lee et al 2002).'

NZEPA ignored the problem of the persistence of chlorpyrifos and its metabolites in work environments to pre-conception and pregnant women. Slow degradation and repeated exposures to workers re-entering premises on a daily basis after spraying, and families living near sprayed fields was downplayed.

> 'the half-life of chlorpyrifos in soil ranges from 20 to 120 days, with the formation of 3,5,6-trichloro-2-pyridinol (3,5,6-TCP) as the main degradation product. Other data indicate that the half-life can range from 2 weeks to more than 1 year [17]. This high interchangeability of the half-life is related to the soil properties, which include the soil type, pH, moisture, temperature, organic matter and organic carbon content, and the microbial metabolism of CPF. The degradation of CPF is increased by higher soil temperatures with lower organic matter contents and lower acidity. Another important factor is the characteristics of the chlorpyrifos-based plant protection product (e.g., its composition, surfactant content, and other auxiliary compounds) and its method of application'[20]

Because of the failure to address risk in pregnancy, and risk to the foetus, the previously set toxicological reference values of chlorpyrifos (EFSA, 2014): ADI 0.001 mg/kg bw per day, AOEL 0.001 mg/kg bw per day cannot apply.

PSGR finds the scientific reasoning by the NZEPA and APVMA to be poorly constructed and unfit for purpose.

PSGR recognise that as a small regulator, it is practical that the NZEPA follows regulatory decision-making on risk and hazard in other jurisdictions with more resources. NZEPA's scientific evidence supplied in support of their APP204694 proposal demonstrates that the NZEPA are unwilling to:

1. Scientifically examine the basis of decisions from the agencies that they most claim to defer to; and
2. Reflect this reasoning in their communications to the public.
3. Highlight the role of epidemiological studies and the role of publicly available literature in supporting the decision-making of these jurisdictions.
4. Incorporate risk from dietary burdens into their assessment.
5. Articulate the issue of uncertainty and a precautionary approach where evidence is plausible.
6. Take into account the absence of data to derive a safe exposure level for the populations most at risk – preconception and pregnant women and infants and young children.

RECOMMENDATION

PSGR recommends that to ensure the protection of pregnant women, infants and children from chlorpyrifos exposures, and the risk from bioaccumulation of breakdown metabolites, that New Zealand follows the European precedents and adopts a 0.01 mg/kg maximum permitted level.

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[2] NZEPA (2024) Science memo: APP204694 chlorpyrifos. October 2024. https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP204694/APP204694_Science_memo_-chlorpyrifos.pdf

[3] NZEPA 2012. Consultation Report. November 2012. https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP201045/c306354078/APP201045-Consultation-Report.pdf

[4] NZEPA (2012) Evaluation and Review Report. https://www.epa.govt.nz/assets/FileAPI/hsno-ar/APP201045/13c074049d/APP201045-APP201045-Evaluation-and-Review-report.pdf

[5] USEPA (2020) https://www.regulations.gov/document/EPA-HQ-OPP-2008-0850-0944

[6] USEPA (2015) https://www.regulations.gov/document/EPA-HQ-OPP-2010-0119-0020

[7] EFSA (European Food Safety Authority), 2019a. Statement on the available outcomes of the human health assessment in the context of the pesticides peer review of the active substance chlorpyrifos. EFSA Journal July 2019, 17(8):5809, 23 pp. https://doi.org/10.2903/j.efsa.2019.5809l

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[9] European Commission Pesticides Residue Database. https://ec.europa.eu/food/plant/pesticides/eu-pesticides-database/start/screen/mrls

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[11] APVMA (2024) Final Review Technical Report September 2024. https://www.apvma.gov.au/sites/default/files/2024-10/Chlorpyrifos%20Final%20Review%20Technical%20Report.pdf

[12] APVMA (2024). Chlorpyrifos uses – summary of assessment outcomes in the final regulatory decision October 2024. https://www.apvma.gov.au/sites/default/files/2024-10/Chlorpyrifos%20uses%20%E2%80%93%20summary%20of%20assessment%20outcomes%20in%20final%20regulatory%20decision.pdf

[13] Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023 made under section 7A of the Agricultural and Veterinary Chemicals (Administration) Act 1992. Compilation No. 6 Compilation date: 9 November 2024 Includes amendments: F2024L01413

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[15] Li Y, Wang X, Feary McKenzie J, 't Mannetje A, Cheng S, He C, Leathem J, Pearce N, Sunyer J, Eskenazi B, Yeh R, Aylward LL, Donovan G, Mueller JF, Douwes J. Pesticide exposure in New Zealand school-aged children: Urinary concentrations of biomarkers and assessment of determinants. Environ Int. 2022 May;163:107206. doi: 10.1016/j.envint.2022.107206. Epub 2022 Apr 5. PMID: 35395578.

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APPENDIX

Australian Pesticides and Veterinary Medicines Authority (APVMA) residue levels for chlorpyrifos and chlorpyrifos-methyl.

Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023 made under section 7A of the Agricultural and Veterinary Chemicals (Administration) Act 1992. Compilation No. 6 Compilation date: 9 November 2024 Includes amendments: F2024L01413

Chlorpyrifos

VS 0621	Asparagus	T0.5
FI 0326	Avocado	0.5
FI 0327	Banana	T0.5
FB 0020	Blueberries	*0.01
VB 0040	Brassica (cole or cabbage) vegetables, head cabbages, flowerhead brassicas	T0.5
FB 2005	Cane berries	T*0.01
VR 0463	Cassava	T*0.02
VS 0624	Celery	T5
GC 0080	Cereal grains {except Sorghum}	T0.1
FC 0001	Citrus fruits	T0.5
SB 0716	Coffee beans	T0.5
SO 0691	Cotton seed	0.05
OC 0691	Cotton seed oil, crude	0.2
DF 0167	Dried fruits	T2
MO 0105	Edible offal (mammalian)	T0.1
PE 0112	Eggs	T*0.01
HS 0784	Ginger, root	*0.02
FB 0269	Grapes	T1
FI 0341	Kiwifruit	2
VA 0384	Leek	T5

Agricultural and Veterinary Chemicals (MRL Standard for Residues of Chemical Products) Instrument 2023 41

Compilation No. 6 Compilation date:9 November 2024

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COMPOUND	FOOD	MRL (mg/kg)
FI 0345	Mango	*0.05
MM 0095	Meat (mammalian) [in the fat]	T0.5
ML 0106	Milks [in the fat]	T0.2
SO 0088	Oilseed {except Peanut}	T0.01
FT 0305	Olives	T*0.05
HH 0740	Parsley	0.05
FI 0351	Passion fruit	*0.05
SO 0697	Peanut	T*0.01
VO 0445	Peppers, sweet [capsicum]	T1
FI 0352	Persimmon, American	T1
FP 0307	Persimmon, Japanese	T1
FI 0353	Pineapple	T0.5
FP 0009	Pome fruits {except Persimmon, Japanese}	T0.5
VR 0589	Potato	0.05
PM 0110	Poultry meat [in the fat]	T0.1
PO 0111	Poultry, edible offal of	T0.1
GC 0651	Sorghum	T3
FI 0367	Star apple	T*0.05
FS 0012	Stone fruits	T1
FB 0275	Strawberry	0.05
GS 0659	Sugar cane	T0.1
VR 0497	Swede	T0.3
VR 0508	Sweet Potato	T0.05
VR 0505	Taro	0.05
VO 0448	Tomato	T0.5
TN 0085	Tree nuts	T0.05
	Vegetables {except Asparagus; Brassica vegetables; Cassava; Celery; Leek; Peppers, sweet [capsicum]; Potato; Swede; Sweet potato; Taro; Tomato}	T*0.01

Chlorpyrifos-methyl		
GC 0080	Cereal grains {except Rice}	10
SO 0691	Cotton seed	*0.01
MO 0105	Edible offal (mammalian)	*0.05

COMPOUND	FOOD	MRL (mg/kg)
PE 0112	Eggs	*0.05
VD 0545	Lupin (dry)	10
MM 0095	Meat (mammalian) [in the fat]	*0.05
ML 0106	Milks [in the fat]	*0.05
SO 0088	Oilseed {except Cotton seed}	0.15
PM 0110	Poultry meat [in the fat]	*0.05
PO 0111	Poultry, edible offal of	*0.05
VD 0070	Pulses {except Lupin (dry)}	0.15
CM 0654	Wheat bran, unprocessed	20
CF 1210	Wheat germ	30

UNITED STATES

§ 180.419 Chlorpyrifos-methyl; tolerances for residues.

(a) *General.* (1) Tolerances are established for the combined residues of the insecticide chlorpyrifos-methyl [*O,-O,-*dimethyl *O*-(3,5,6-trichloro-2-pyridyl)] phosphorothioate and its metabolite (3,5,6-trichloro-2-pyridinol) in or on the following food commodities:

Commodity	Parts per million
Barley, grain	6.0
Cattle, fat	0.5
Cattle, meat	0.5
Cattle, meat byproducts	0.5
Egg	0.1
Goat, fat	0.5
Goat, meat	0.5
Goat, meat byproducts	0.5
Hog, fat	0.5
Hog, meat	0.5
Hog, meat byproducts	0.5
Horse, fat	0.5
Horse, meat	0.5
Horse, meat byproducts	0.5
Milk, fat (0.05 ppm (N) in whole milk	1.25
Oat, grain	6.0
Poultry, fat	0.5
Poultry, meat	.5
Poultry, meat byproducts	.5
Rice, grain	6.0
Sheep, fat	0.5
Sheep, meat	0.5
Sheep, meat byproducts	0.5
Sorghum, grain	6.0
Wheat, grain	6.0

(2) Tolerances are established for the combined residues of the insecticide chlorpyrifos-methyl (*O,-O-* dimethyl- *O-*(3,5,6-trichloro-2-pyridyl) phosphorothioate and its metabolite (3,5,6-trichloro-2-pyridinol) in or on the following food commodities when present therein as a result of application to stored grains:

Commodity	Parts per million
Barley, bran	90
Barley, pearled barley	90
Rice, bran	30
Rice, hulls	30
Rice, polished rice	30
Sorghum, grain, bran	90
Wheat, bran	30
Wheat, germ	30
Wheat, middlings	30
Wheat, shorts	30

(b) *Section 18 emergency exemptions.* [Reserved]

(c) *Tolerances with regional registrations.* [Reserved]

(d) *Indirect or inadvertent residues.* [Reserved]

[65 FR 33715, May 24, 2000, as amended at 74 FR 46374, Sept. 9, 2009]