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Cancelling pesticide registrations and revoking tolerances: The case of chlorpyrifos



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ABSTRACT

Petitions submitted to the United States Environmental Protection Agency (EPA) have sought to cancel registrations of chlorpyrifos and to revoke chlorpyrifos tolerances in or on food due to adverse health effects on people. Under federal law, tolerances for pesticide chemical residues in or on food must provide with reasonable certainty that no harm will result from a person's aggregate exposure. Petitioners' claims are analyzed under the legal requirements to discern whether the EPA had a rational basis for issuing its 2017 Chlorpyrifos Order denying the requests for cancellation of registrations and revocation of tolerances. The scientific evidence considered by the EPA indicated that existing tolerances do not protect people from unsafe levels of chlorpyrifos. Under the Federal Food, Drug, and Cosmetic Act, tolerances need to be revoked if they do not protect human health. In refusing to recognize that chlorpyrifos tolerances do not comply with federal law, the EPA's 2017 Chlorpyrifos Order appears to be arbitrary and capricious.

1. Introduction

Pesticides have revolutionized the control of pests that have plagued mankind for millennia. An evaluation of today's food production, food safety, and disease control endeavors affirms a conclusion that our society is very dependent on pesticide use. Worldwide, firms sell nearly 2.7 billion kg of active ingredients annually (EPA, 2017c). In the United States, nearly 500,000 kg are being used per year which equates to approximately 1.5 kg per person (EPA, 2017c). Because pesticides are poisonous, governments need to be vigilant in their oversight of pesticides and draw upon science to develop appropriate protocols to maintain an equilibrium between beneficial use and harmful externalities. In the United States, the Federal Fungicide, Insecticide, and Rodenticide Act (FIFRA) delineates provisions for the registration of pesticides to regulate use (U.S. Code, 2016). The Environmental Protection Agency (EPA) oversees the registration process.

Operational applications of pesticides can be hazardous to humans and other nontarget organisms. FIFRA forbids the registration of pesticides that present unreasonable risks to people and the environment through the application of a cost-benefit analysis. Costs include exposure to pesticide residues that might harm people. To prevent situations in which pesticide chemical residues in or on food present health hazards to humans, the Federal Food, Drug, and Cosmetic Act (FDCA) prescribes maximum residue limits called tolerances (U.S. Code, 2016). The Food and Drug Administration administers this act. If exposure to a chemical pesticide residue in or on food items is unsafe,

under the FDCA the tolerance needs to be revoked.

After a pesticide is registered, new scientific studies may disclose that a registered pesticide is associated with additional risks of harm to humans and the environment. In some cases, the new information may support the cancellation of pesticide use. U.S. law delineates a cancellation procedure to terminate the sale and use of a registered pesticide (U.S. Code, 2016), and a perusal of the Federal Registrar shows the EPA officially cancelling hundreds of pesticides (EPA, 1992). For most pesticide cancellations, registrants can no longer sell these products and producers have to find an alternative pest control (National Corn Growers Association v. EPA, 2010). However, federal regulations allow an unregistered pesticide to be distributed or sold under an emergency exemption (U.S. Code of Federal Regulations, 2017, tit. 40, §152.30). The EPA database for apples lists 49 emergency exemptions requested since 2010, with most of them allowing applications for a few months (EPA, 2017d).

Because the scientific studies and information used in making decisions about permissible pesticide uses do not always lead to obvious conclusions, the regulatory decisions by the EPA can be controversial. Registrants and users have financial interests linked to the use of pesticides while others, including environmental groups, want to deter harm. Adversely affected persons (including environmental groups) may turn to the judiciary to settle a dispute. Several major legal challenges attest the difficulties in interpreting scientific evidence for regulatory actions involving pesticide use (Table 1).

One example of a legal challenge involves the use of chlorpyrifos.

Table 1
Recent challenges to pesticide registrations, tolerance levels, and cancellations for pesticide residues.

Litigation and year	Pesticide	Concern	
National Corn Growers Association v. EPA (2010)	Carbofuran	Revoking tolerances	
NRDC v. EPA (2011)	Dichlorvos	Revoking tolerances	
Northwest Coalition for Alternatives to Pesticides v. EPA (2012)	Organophosphates	Flawed biological opinion	
Pollinator Stewardship Council v. EPA (2015)	Sulfoxaflor	Challenging registration	
In re Pesticide Action Network North America (2015)	Chlorpyrifos	Revoking tolerances and cancelling registrations	
In re Bayer CropScience LP (2016)	Flubendiamide	Cancelling registrations	
In re Pesticide Action Network North America (2017)	Chlorpyrifos	Revoking tolerances and cancelling registrations	
Ellis v. Housenger (2017)	Clothianidin and thiamethoxam	Challenging registrations	

The Natural Resources Defense Council (NRDC) and other petitioners have petitioned to cancel registrations and revoke tolerances of chlorpyrifos. Chlorpyrifos (O,O-Diethyl O-3,5,6-trichloropyridin-2-yl phosphorothioate) is a broad-spectrum, chlorinated organophosphate pesticide used to control insect, tick, and mite populations. The NRDC's petition illustrates a controversy in the EPA's interpretation and acceptance of scientific data. In 2015, the EPA examined scientific studies and concluded that aggregate exposures to chlorpyrifos meant that chemical residues in or on food were not safe (EPA, 2015). Subsequently, the agency declined to acknowledge this evidence and issued an order declining to revoke tolerances or cancel registrations of chlorpyrifos (EPA, 2017a).

This paper analyzes the regulatory framework governing the revocation of chlorpyrifos tolerances and the cancellation of registrations. For chlorpyrifos residues in or on food, the FDCA requires the EPA to cancel tolerances if exposure is likely to pose a potential health risk from dietary exposure. Due to new evidence of significant harm from chlorpyrifos not considered at the time of registration, it should be concluded that the EPA needs to revoke chlorpyrifos tolerances. With the revocation of tolerances, it is likely that some chlorpyrifos registrations should be cancelled.

2. Chlorpyrifos use

Chlorpyrifos is an organophosphate insecticide that was initially registered in the United States in 1965 to control foliage- and soil-borne pests (EPA, 2002; Li et al., 2015; Ray et al., 2009). Chlorpyrifos became a very popular pesticide and was used in many indoor, outdoor, and agricultural settings (EPA, 2000b). Yet, the history of the regulation of this pesticide by the EPA shows that, after its registration, additional risks and harm have been identified (Table 2). By 1974, its danger to

Table 2 Abbreviated history in the regulation of chlorpyrifos.

1965 Registered for usage as a pesticide 1974 Initial petition for tolerance levels 1979 Adoption of a food additive regulation in food-handling establishments 1979 Adoption of a feed additive regulation 1989 Adoption of more protective air contamination standards 1992 Initial request to cancel a registration for Dursban* EPA (1989) 1994 Classified as a toxic chemical for listing under the Emergency Planning and Community Right-to-Know Act and the Pollution Prevention Act of 1990 2000 Various use deletions and cancellations as requested by registrants 2007 NRDC petition to revoke tolerances and cancel NRDC (2007) 1994 Repaired to the registration of dichlorvos 2011 Challenge to the registration of dichlorvos 2012 EPA response maintaining registrations for dichlorvos EPA (2011) 2012 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe 2017 EPA denies NRDC's petition EPA (2017a)	Year	Action	Source
Adoption of a food additive regulation in food-handling establishments 1979 Adoption of a feed additive regulation 1989 Adoption of a feed additive regulation 1980 Adoption of more protective air contamination standards 1992 Initial request to cancel a registration for Dursban* EPA (1989) 1994 Classified as a toxic chemical for listing under the Emergency Planning and Community Right-to-Know Act and the Pollution Prevention Act of 1990 2000 Various use deletions and cancellations as requested by registrants 2007 NRDC petition to revoke tolerances and cancel NRDC (2007) registrations 2011 Challenge to the registration of dichlorvos 2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	1965	Registered for usage as a pesticide	EPA (2000b)
establishments 1979 Adoption of a feed additive regulation 1989 Adoption of more protective air contamination standards 1992 Initial request to cancel a registration for Dursban* EPA (1989) 1994 Classified as a toxic chemical for listing under the Emergency Planning and Community Right-to-Know Act and the Pollution Prevention Act of 1990 2000 Various use deletions and cancellations as requested by registrants 2007 NRDC petition to revoke tolerances and cancel NRDC (2007) registrations 2011 Challenge to the registration of dichlorvos NRDC v. EPA (2011) 2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	1974	Initial petition for tolerance levels	EPA (1974)
1989 Adoption of more protective air contamination standards 1992 Initial request to cancel a registration for Dursban* EPA (1992) 1994 Classified as a toxic chemical for listing under the Emergency Planning and Community Right-to-Know Act and the Pollution Prevention Act of 1990 2000 Various use deletions and cancellations as requested by registrants 2007 NRDC petition to revoke tolerances and cancel registrations 2011 Challenge to the registration of dichlorvos 2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	1979		EPA (1979a)
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Emergency Planning and Community Right-to-Know Act and the Pollution Prevention Act of 1990 2000 Various use deletions and cancellations as requested by registrants 2007 NRDC petition to revoke tolerances and cancel NRDC (2007) registrations 2011 Challenge to the registration of dichlorvos NRDC v. EPA (2011) 2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	1992	Initial request to cancel a registration for Dursban®	EPA (1992)
and the Pollution Prevention Act of 1990 2000 Various use deletions and cancellations as requested by registrants 2007 NRDC petition to revoke tolerances and cancel NRDC (2007) registrations 2011 Challenge to the registration of dichlorvos NRDC v. EPA (2011) 2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	1994	Classified as a toxic chemical for listing under the	EPA (1994)
2000 Various use deletions and cancellations as requested by registrants 2007 NRDC petition to revoke tolerances and cancel NRDC (2007) registrations 2011 Challenge to the registration of dichlorvos NRDC v. EPA (2011) 2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe		Emergency Planning and Community Right-to-Know Act	
registrants 2007 NRDC petition to revoke tolerances and cancel registrations 2011 Challenge to the registration of dichlorvos NRDC v. EPA (2011) 2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe		and the Pollution Prevention Act of 1990	
registrations 2011 Challenge to the registration of dichlorvos Challenge to the registration of dichlorvos EPA (2011) 2012 EPA response maintaining registrations for dichlorvos EPA (2012) EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	2000	· · · · · · · · · · · · · · · · · · ·	EPA (2000b)
2012 EPA response maintaining registrations for dichlorvos EPA (2012) 2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	2007	÷	NRDC (2007)
2015 EPA cannot determine that aggregate exposure to residues of chlorpyrifos are safe	2011	Challenge to the registration of dichlorvos	THE C TI LITT
residues of chlorpyrifos are safe	2012	EPA response maintaining registrations for dichlorvos	EPA (2012)
**	2015	00 0 1	EPA (2015)
2017 EPA denies NRDC's petition EPA (2017a)			
	2017	EPA denies NRDC's petition	EPA (2017a)

humans was recognized as disclosed by a petition for tolerance levels (EPA, 1974). In 1979 and 1989, regulations were adopted to reduce the risks of harm from chlorpyrifos use.

In 1997, it was recognized that some indoor uses of chlorpyrifos were unsafe (EPA, 2002). Given this information, the EPA was able to have registrants of products containing chlorpyrifos agree to cancel their registrations in 2000 (EPA, 2000a). Other overly-broad registrations of chlorpyrifos were voluntarily cancelled in 2003 (EPA, 2003). The cancellations included all termite control uses, most residential uses, many indoor nonresidential uses, many outdoor nonresidential sites, and use on tomatoes and post-bloom apple trees (EPA, 2000b). In addition, some registrants agreed to limit the maximum label application rate for outdoor nonresidential uses and to prevent homeowners from buying remaining chlorpyrifos products (EPA, 2000a, 2000b).

The most serious adverse effect of chlorpyrifos use is that this pesticide is moderately hazardous to humans (WHO, 2010). Chlorpyrifos is a neurotoxin and its mode of action involves binding to and inhibiting the enzyme cholinesterase that regulates nerve functioning (Pope et al., 2005). Depending on the level of cholinesterase inhibition, chlorpyrifos exposure can result in a spectrum of symptoms ranging from nausea, dizziness, confusion and death (EPA, 2002, 2011).

Risk assessments suggest that exposure is particularly dangerous for pregnant women, infants, and young children (Bouchard et al., 2010; Silver et al., 2017). Exposure of expectant mothers to chlorpyrifos has adverse effects on fetal growth, birth outcomes, and neurodevelopment of children (Cole et al., 2014; de Gavelle et al., 2016; Harley et al., 2011; Rauh et al., 2015; Whyatt et al., 2005). Routine exposure in residential settings to organophosphates has a measurable effect on the brain structure of children, cognitive performance, social development, and attention spans (Furlong et al., 2014; Lovasi et al., 2011; Rauh et al., 2012; Slotkin and Seidler, 2007a,b; Zhang et al., 2014). Studies of human cell cultures and children suggest that exposure may be linked to developmental disorders, autoimmune disorders, and an increase in the probability of chromosomal aberrations (Fortenberry et al., 2014; Li et al., 2015). It also has been linked to poorer cognitive development and Alzheimer's disease (Cole et al., 2014; Peris-Sampedro et al., 2014).

In 2014 and 2016, panels of EPA scientists evaluated studies of human health risk assessments for chlorpyrifos (EPA, 2014c, 2016b). They found that exposure was negatively affecting humans:

there is evidence of delays in mental development in infants (24–36 months), attention problems and autism spectrum disorder in early childhood, and intelligence decrements in school age children who were exposed to [organophosphates] during gestation (EPA, 2016b).

Prenatal chlorpyrifos exposure resulted in increased numbers of abnormal primitive reflexes and impaired neurobehavioral development in children (de Gavelle et al., 2016; Whyatt et al., 2004, 2007; Young et al., 2005). In 2015, the EPA proposed revoking tolerances for chlorpyrifos, but in 2017, the agency entered an order to allow the continued use of these pesticides (EPA, 2015, 2017a).

3. Pesticide registration, cancellation, and tolerances

Governments regulate the use of pesticides because they are toxic

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