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Superficial Safeguards: Most Pesticides Are Approved by Flawed EPA Process

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Conditional registration approves some pesticides before they have been rigorously tested. They end up in some of our most basic household items.

The public may think pesticides are only allowed onto store shelves and for use in agriculture and into consumer products if they have been approved by the U.S. Environmental Protection Agency (EPA) in a transparent and scientifically rigorous process. Recent investigations by the Natural Resources Defense Council (NRDC), however, reveal a deeply flawed system, indicating that the public's trust is misplaced. NRDC spent several years examining federal government data and interviewing key officials, and has determined that the government has allowed the majority of pesticides onto the market without a public and transparent process and in some cases, without a full set of toxicity tests, using a loophole called a conditional registration. In fact, as many as 65 percent of more than 16,000 pesticides were first approved for the market using this loophole. This issue brief explains how the conditional registration program differs from full registration and provides case studies of two pesticides—nanosilver and clothianidin—to show how the conditional registration has been misused. The case of nanosilver, approved by the EPA as an antimicrobial agent in textiles, highlights the ways that some new pesticides can obtain a conditional registration without thorough toxicity testing to evaluate risk. The case of clothianidin—a pesticide that is designed to be absorbed into plant tissue but is then unintentionally passed on to bees and other pollinators, and consequently is linked to widespread bee deaths—illustrates the types of problems that may arise after a pesticide has been conditionally approved, and are often hidden from public scrutiny. Finally, NRDC has found significant shortcomings in the EPA's data-gathering system. We cannot determine how many pesticides were first conditionally approved, allowed onto the market, and then lingered there for years while toxicity testing data was being submitted; or how many pesticides were subsequently withdrawn for various reasons; or how many were given full registration.

PESTICIDE REGISTRATION

Pesticides are poisons. They are designed to kill things. Unfortunately, they often harm more than the intended targets, such as weeds or insects; they can also harm, or even kill, non-target species, including frogs, fish, birds, bees, other beneficial insects, and people. Recognizing this danger decades ago, Congress passed the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which requires that all pesticides be registered by the EPA before they can be legally sold or distributed in the United States. Under FIFRA, the EPA cannot register a pesticide until it ensures that the pesticide's use will not pose unreasonable adverse effects on the environment or human health. The EPA currently interprets this provision to mean that some level of harm is allowed. For example, the EPA often considers the risk of one person out of 1 million getting cancer to be acceptable.

By law, to register a pesticide, a company must submit results from a list of specified studies to the EPA. These results make up the core data that help the EPA determine human exposure, effects on human health and wildlife, and environmental fate. The government uses these data to determine whether or how the pesticide can be used without endangering human health or the environment.

The EPA may also consider data from peer-reviewed scientific journals, other governments, or other sources, oftentimes receiving these additional sources from public comments. This whole process can last several years and includes data review by the agency's in-house science experts, opportunities for public comment, and discussions with the registrant and grower groups.

In 1972, Congress amended FIFRA to impose more stringent testing requirements to register pesticides. Registrants subsequently struggled to meet the new data requirements by the law's deadlines. To address this problem, Congress in 1978 created the conditional registration procedure with the intention that it would be used only in rare, specific instances.

THE CONDITIONAL REGISTRATION

Even though industry often claims that all registered pesticides have been thoroughly assessed, the EPA has used conditional registration as a loophole to register some pesticides without all the necessary data. The conditional registration allows a new active ingredient to enter the market for an unspecified period of time during which the registrant must generate missing data requested by the EPA.[1] By law, to grant an active ingredient conditional registration, the EPA must determine that 1) the registrant did not have sufficient time to generate the required data because not enough time has passed since the data requirement was imposed; 2) the use of the pesticide during this time will not cause any unreasonable adverse effect on the environment; and 3) the use of the pesticide is in the public interest, such as to prevent a disease outbreak.[2] Properly used, conditionally registering a new pesticide provides an important benefit in special situations such as allowing new pesticides on the market to address a public health emergency. However, improper use of conditional registration means that scores of untested or undertested pesticides may litter the market, potentially threatening human health.

THE ENVIRONMENTAL PROTECTION AGENCY IS MISUSING CONDITIONAL REGISTRATIONS

Despite the intention of Congress that conditional registration be used sparingly, NRDC's investigations of the EPA's pesticide registration database revealed that as of August 2010, more than 11,000—about 65 percent—of the 16,000-plus currently active pesticide products have been conditionally registered and allowed on the market.[3] Soon after NRDC submitted its findings to the EPA, the agency conducted its own analysis, and confirmed NRDC's findings.[4]

For pesticides registered between 2004 and 2010, the EPA's own analysis found that it had misused the conditional registration provision for other registration activities such as "requiring label changes" and other actions that are "beyond the scope" of the conditional registration.[5] In fact, according to the EPA's analysis, they misused it 98 percent of the time.[6] In 2011 and 2012, of more than 1,400 new registrations, 300-plus pesticides were conditionally registered—about 20 percent overall—a dramatically reduced rate from previous years, but still too many for comfort. By examining EPA data, NRDC has determined that as of October 2012, conditionally registered pesticide products still made up about 65 percent (10,640 out of 16,500) of total pesticide registrations.

THE ENVIRONMENTAL PROTECTION AGENCY IS NOT TRACKING CONDITIONAL REGISTRATIONS

The EPA's database is seriously disorganized. Once a pesticide is conditionally registered, the EPA does not have a system to track the data it had requested as a condition of the registration. In addition, the agency does not follow whether those data were received, what the data show regarding the pesticide's potential for harm or other aspects of the registration decision, or what, if any, changes were made in response to the received data. These problems suggest that conditional registrations may last many years with no trigger to remind the EPA to review the status of the required studies or assess their meaning.

The EPA defends the integrity of its conditional registration program by noting that between 2004 and 2010, it had never altered its previous regulatory decision for any conditional registrations based on the subsequent data it received, suggesting that all its conditional decisions were right to begin with. However, there is no public notice of, or comment period on, the EPA's ultimate decision. The lack of both tracking and public engagement makes it impossible to know 1) if the requested studies were submitted in a timely manner; 2) whether the submitted studies were reliably conducted; 3) if the EPA's conclusions concerning safety were well-founded; and 4) if the EPA should have altered its regulatory decision for any of those pesticides. This process lacks accountability and transparency and compromises the public trust.

Given the poor tracking, lack of public accountability, absence of a transparent process, the failure to provide a public response to submitted data, and the failure to provide a public notice and comment period, the EPA's use of conditional registrations to usher inadequately assessed pesticides onto the market is an abdication of the agency's duty to protect public health and the environment.

Two case studies of pesticides—nanosilver and clothianidin—highlight a conditional registration program gone wrong. Nanosilver is toxic to brain cells and its use on clothing will lead to exposures to people, including pregnant women and children; it is a significant public health concern. Clothianidin comes from a family of pesticides connected to widespread bee deaths, but was approved based on a poorly conducted bee field test, which will be discussed later in this report.

THE ENVIRONMENTAL PROTECTION AGENCY INAPPROPRIATELY GRANTED CONDITIONAL REGISTRATION TO NANOSILVER FOR USE IN TEXTILES

Nanosilver—particles of silver that are in the nanometer size range—is claimed to kill bacteria, and therefore must be registered as a pesticide by the EPA.

Nanosilver is different from conventional silver because of its small size. This difference raises many concerns, particularly considering the ability of nanosilver to travel through the body and damage cells in the brain, liver, stomach, testes, and other organs, as well as pass from mother to fetus.

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Conventional silver has long been known to be an effective germ killer and has been registered since the 1950s as an antimicrobial pesticide used to inhibit bacteria growth in water filters and to control algae in swimming pools.[7] Although conventional silver is not very harmful to humans, it is highly toxic to microbes and aquatic organisms, and the toxic silver ions (Ag+) are persistent in the environment. Nanosilver particles share these properties with conventional silver, making it an effective antimicrobial agent that kills harmful microorganisms, like germs, as well as beneficial microorganisms, such as daphnia and algae, that are critical in the food web.

Although sharing many hazardous properties with conventional silver, nanosilver particles raise the additional concern that the smaller size means the nanoparticle and its ions can access places that conventional silver cannot. Laboratory rodent studies suggest that if breathed or swallowed, for example, by workers using nanosilver powders to treat fabrics or families using sterilizing sprays and nanosilver air fresheners, the particles could travel throughout the body, ending up in the testes, liver, kidney, lungs, brain, stomach, and other organs, where they may damage cells and compromise organ function.[8]

In 2008, Swiss company HeiQ Materials Ag applied to the EPA to register nanosilver as a preservative in textiles such as clothing, bed sheets, pillowcases, and blankets. This application represented the first pesticide to be registered as a nano-size chemical. Other consumer products use nanosilver unlawfully because they have not gone

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through the legally-required registration process.[9] The EPA determined that nanosilver is different from silver, meaning that HeiQ needed to go through a full registration process and submit data on the toxicity of nanosilver, rather than applying under the existing registration of conventional silver.[10] Since HeiQ had not yet conducted many of the necessary studies, the EPA granted the company a conditional registration in 2011, allowing the product onto the market while HeiQ undertook the research. Among the absent studies required as a condition of the registration were those looking at reproductive and developmental toxicity, inhalation toxicity, dermal toxicity, and chromosomal damage.

In granting a conditional registration for nanosilver in textiles, the EPA acknowledged that people will be in direct contact with nanosilver from these textiles, including workers who make the clothing, consumers who use and wear it, and infants and babies who lay against it, and suck or chew their parents' treated clothing. (Nanosilver leaches from clothing into wash water and has been shown to go from treated clothing onto skin in laboratory tests using artificial skin.[11])

The EPA claimed that allowing this product onto the market while awaiting the toxicity studies would benefit the public interest by reducing the overall environmental load of silver because of its smaller size. However, nanosilver is not only replacing conventional silver uses, but also being sold for new and expanded markets, resulting in the release of far more nanosilver and toxic silver ions into sewage and water treatment systems, and ultimately into rivers, streams, and other receiving waters. Consumers can now buy pillows and shirts that contain nanosilver without any warning labels about toxicity concerns. Furthermore, if nanosilver proves to be much more toxic than conventional silver, the smaller quantities released will not necessarily cause less harm.

THE ENVIRONMENTAL PROTECTION AGENCY ALLOWS CONTINUED USE OF CLOTHIANIDIN DESPITE FLAWED STUDIES

Pollinators, including bees, bats, and butterflies, contribute approximately $15 billion to the economy through the pollination of more than 130 cash crops, which make up approximately one-quarter of all the foods in the human diet, including almonds, cherries, pumpkins, and apples.[12] Unfortunately, beekeepers have been suffering dramatic bee colony losses of about 30 percent annually since 2007, likely from a combination of environmental stressors, parasites, pathogens, and pesticide residues in bee hives.[13]

Clothianidin is one in a family of neonicotinoid pesticides that are key suspects in these losses because they are systemic (taken up and distributed throughout the plant tissue, including its pollen and nectar), long-lasting, and highly toxic to honey bees.[14] Bayer CropScience was granted a conditional registration in 2003 for clothianidin to treat corn seed and canola seed. The registration was conditioned upon, among other things, the submission of a field study of the effects on bees by 2004. Bayer not only conducted a defective study but also submitted findings three years late.

The EPA had required the pollinator field test to include a complete worker-bee life cycle study and an evaluation of the exposure to and effects of clothianidin on the queen bee. The study, submitted in 2007, was so poorly undertaken that the EPA considered it to be invalid (though it later slightly upgraded it to "supplemental" because of some limited redeeming information it provided).[15]

Bayer's study concluded that clothianidin had no effect on bee mortality. The study had numerous flaws; the most egregious ones noted by the EPA reviewers state that 1) the treated and control (no pesticide) fields were too close together, and bees likely foraged among all fields, resulting in cross-contamination of treated and control hives; and 2) the study likely undercounted dead bees by using a faulty "sheet method" instead of the EPA-recommended, more accurate bee trap. Because of these and other flaws, both treated and control fields had significant bee deaths.[16] Because Bayer failed to provide its raw data, the EPA could not conduct a statistical reanalysis of the study results, meaning that the EPA and the public must rely on the data analysis provided by Bayer rather than being able to scrutinize the data using alternate assumptions and approaches.[17] In fact, Health Canada, the Canadian agency that regulates pesticides, found that "mortality in worker bees was obviously higher in clothianidin-treated colonies" when only dead-bee traps data were used in the analysis.[18] Design flaws make it almost impossible to determine the risks from clothianidin to bee survival.[19] Despite these issues, in April 2010 clothianidin's registration was switched from conditional to fully registered. A November 2010 EPA memo determined that Bayer's field study was deficient, but clothianidin remains fully registered today.

The EPA had conditioned clothianidin's registration on an informative final study, which never materialized. Moreover, the public never had a chance to comment on the study or the EPA's conditional registration decision. Yet the insecticide remains registered and on the market, thanks to the use of the conditional registration loophole.

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RECOMMENDATIONS

The EPA is conditionally registering pesticides with inadequate or absent data. Further, subsequent EPA determinations about whether the conditions imposed on registrants have been satisfied are made in private without any opportunity for the public to comment. Ultimately, conditional registration of pesticides is not a temporary and rare occurrence as Congress intended, but a wide loophole that pesticide manufacturers use to get many products onto the market before they are proven safe to the public. The EPA's own website acknowledges that it needs improved registration tracking and staff training to avoid continued misuse and overuse of the conditional registration provision.[20]

NRDC recommends that the EPA take the following steps to respond to and improve its grievously flawed practices in pesticide registration:

1. **Review all previously conditionally registered pesticides and bring them into compliance with the law and with the recommendations of this report**. In the course of its review of conditional registrations triggered by NRDC's inquiries, it appears the EPA has never received data for some of the conditional registrations.

2. **Immediately cancel pesticide registrations with overdue studies or those that are out of compliance for any other reason.** The EPA should immediately cancel the registrations for clothianidin and nanosilver.
3. **Properly document conditional registration actions.** One of the most fundamental problems identified in the NRDC study and by the EPA is that the agency does not have systematic tracking and management systems for conditional registrations.[21] Addressing this should be an immediate priority for the EPA, so it can provide a credible and transparent program to the public.
4. **Establish a process where the public can comment on new data received to support a conditional registration.** Currently, once a pesticide is conditionally registered, the public is no longer afforded any opportunity to either track or comment on subsequent data submissions. Lack of data or potential flaws in the follow-up studies are hidden from public scrutiny, depriving the EPA of the insights of scientific experts in the field, and forcing the public to blindly trust the EPA's determinations.
5. **Place all submitted data into a publicly accessible, updated database.** To show that required studies are being submitted for conditional registrations, the EPA should establish a publicly accessible, electronically searchable database that identifies all the actions taken under the agency's conditional registration authority, and the status of those registrations. The database should clearly identify for each conditionally registered pesticide
    - the conditions upon which registration was based
    - the EPA's authority for issuing the conditional registration
    - the time line for the registrant to submit the data
    - the date that the EPA received the required data
    - the Data Evaluation Record or the EPA's summary assessment of the data
    - how the EPA addressed the results of submitted studies in the registration decision

6. **Use the conditional registration process only in the limited and rare circumstances described by Congress.** Congress gave the EPA the authority to limit or even prevent the use of a pesticide where there are scientific uncertainties and data gaps, with the understanding that these chemicals are harmful by design. The EPA must use its authority to protect people, pollinators, and other wildlife, in accordance with its stated mission and obligation as a public health agency.

Endnotes

1 The active ingredient is the chemical in a pesticide product that kills, controls, or repels pests. The same active ingredient may be found in hundreds of pesticide products with different names; Conditional registrations can also be granted to applications for a new end-use product on an already registered pesticide or for a pesticide product that is identical or substantially similar to one that has already been registered. There are fewer requirements to be conditionally registered for these two types of applications.

2 Federal Insecticide, Fungicide, and Rodenticide Act. 7 U.S.C. §136a(c)(7)(C); 42 C.F.R. § 152.114.

3 Sass J, Wu M. Letter to U.S. Environmental Protection Agency. Comments from the NRDC on the proposed conditional registration of a pesticide product HeiQ AGS-20, containing nanosilver. Sept 10, 2010. Federal Docket ID # EPA-HQ-OPP-2009-1012-0061

4 U.S. Environmental Protection Agency, *Conditional Registration—Evaluating Program Use of Conditional Registrations*, April 25, 2011, http://www.epa.gov/pesticides/regulating/conditional-registration.html#evaluating (accessed September 8, 2011).

5 Ibid.

6 Ibid.

7 U.S. Environmental Protection Agency. *Reregistration Eligibility Document Facts: Silver*. EPA-738-F-93-005. U.S. Environmental Protection Agency. June 1993. http://www.epa.gov/oppsrrd1/REDs/factsheets/4082fact.pdf (accessed September 8, 2011).

8 U.S. Environmental Protection Agency, *US EPA Response to Comments Received on Proposed Decision Document for the Registration of HeiQ AGS-20 as a Materials Preservative in Textiles*, December 1, 2011, 34. Federal Docket ID# EPA-HQ-OPP-2009-1012-0065; U.S. Environmental Protection Agency. EPA Decision Document. *Conditional Registration of HeiQ AGS-20 as a Materials Preservative in Textiles,* December 1, 2011. Federal Docket ID# EPA-HQ-OPP-2009-1012-0064; J. H. Sung, Ji, J.H., Park, J.D. et al., "Subchronic Inhalation Toxicity of Silver Nanoparticles," *Toxicological Sciences*, April 2009; 108(2):452-61. doi: 10.1093/toxsci/kfn246; U.S. Environmental Protection Agency, External Review Draft Nanomaterial Case Study: Nanoscale Silver in Disinfectant Spray, August 13, 2010. EPA/600/R-10/081. ; J. H. Sung, Ji, J.H., Song, K.S., Lee, J.H., Choi, K.H., Lee, S.H., Yu, I.J., "Acute Inhalation Toxicity of Silver Nanoparticles," *Toxicology and Industrial Health*, March 2011,; 27(2):149-54. J. H. Ji, Jung, J.H., Kim, S.S., Yoon, J.U., Park, J.D., Choi, B.S., Chung, Y.H., Kwon, I.H., Jeong, J., Han, B.S., Shin, J.H., Sung, J.H., Song, K.S., Yu, I.J., "Twenty-eight Day Inhalation Toxicity Study of Silver Nanoparticles in Sprague-Dawley Rats," *Inhalation Toxicology,* August 2007; 19(10):857-71. M. van der Zande, Vandebriel, R.J., Van Doren, E., Kramer, E., Herrera Rivera, Z., Serrano-Rojero, C.S., Gremmer, E.R., Mast, J., Peters, R.J., Hollman, P.C., Hendriksen, P.J., Marvin, H.J., Peijnenburg, A.A., Bouwmeester, H., "Distribution, Elimination, and Toxicity of Silver Nanoparticles and Silver Ions in Rats After 28-Day Oral Exposure," *ACS Nano*, August 28, 2012; 6(8):7427-42.

9 U.S. Environmental Protection Agency. *Proposed Decision Document for the Registration of HeiQ AGS-20 as a Materials Preservative in Textiles*. 12 August 2010. Federal Docket ID# EPA-HQ-OPP-2009-1012-0020.

10 U.S. Environmental Protection Agency FIFRA Scientific Advisory Panel. Meeting Minutes November 3-5, 2009: Evaluation of Hazard and Exposure Associated with Nanosilver and Other Nanometal Pesticide Products. 26 January 2010. Page 7. http://www.epa.gov/scipoly/sap/meetings/2009/november/110309ameetingminutes.pdf ; U.S. Environmental Protection Agency. Proposed Decision Document for the Registration of HeiQ AGS-20 as a Materials Preservative in Textiles. 12 August 2010. Federal Docket ID# EPA-HQ-OPP-2009-1012-0020.

11 Westerhoff P, Benn TM. "Nanoparticle Silver Released into Water from Commercially Available Sock Fabrics." *Environmental Science & Technology*. 2008;42(11):4133-4139. doi: 10.1021/es7032718; Kulthong, K, Srisung S, Boonpavanitchakul K, Kangwansupamonkon W and Maniratanachote R. "Determination of Silver Nanoparticle Release from Antibacterial Fabrics into Artificial Sweat." *Particle and Fibre Toxicology*. 2010;7(1):8. doi: 10.1186/1743-8977-7-8.

12 Agricultural Research Service. "Questions and Answers: Colony Collapse Disorder." U.S. Department of Agriculture. http://www.ars.usda.gov/News/docs.htm?docid=15572 Updated December 17, 2010. (accessed September 8, 2011).

13 Colony Collapse Disorder Steering Committee, Agricultural Research Service, *Colony Collapse Disorder* Progress Report, June 2010, http://www.ars.usda.gov/is/br/ccd/ ccdprogressreport2010.pdf (accessed September 8, 2011).

14 R. Johnson, *Honey Bee Colony Collapse Disorder*, Congressional Research Service 7-5700, January 7, 2010, http://www.fas.org/sgp/crs/misc/RL33938.pdf. Charles Abel, "Bee Concerns Pose Threat to OSR Viability," *Farmers Weekly*, January 3, 2013, http://www.fwi.co.uk/Articles/03/01/2013/136998/bee-concerns-pose-threat-to-osr-viability.htm (accessed January 4, 2013).

15 EPA memo from J DeCant to K Davis. "Revised assessment for clothianidin registration of Prosper T400 seed treatment on mustard seed (oilseed and condiment) and Poncho/Votivo seed treatment on cotton." 3 December 2010; EPA memo from A Pease to K Davis. "Reclassification of MRID 46907801/46907802 data package 336888 for clothianidin, PC Code 044309." December 22, 2010.

16 The bee trap works by trapping the dead bees as they are expelled from the colony and holding them for counting, whereas the sheet method catches dead bees that fall onto a sheet placed on the ground at the entrance of the hive. The sheet method undercounts dead bees because it loses the dead bees that blow away or get eaten by insects or other animals before someone can get out to the field to count them, a highly likely event since Bayer scientists only counted dead bees once per week instead of daily as EPA had recommended.

17 Email from W Hou, Health Canada to K McCormack, EPA and J DeCant, EPA. "Clothianidin field study." 10 December 2010 (with attachment).

18 "Data Evaluation Record for honey bee field testing for pollinators." Reviewed by EPA: CE Padova, 18 September 2007; TS Myers, 26 September 2007; A Pease, 22 December 2010; T Steeger, 22 December 2010. http://www.epa.gov/pesticides/chemical/foia/cleared-reviews/reviews/044309/044309-090201-113501-079801-2010-12-22a.pdf (accessed September 8, 2011).

19 The study redeemed itself somewhat in that it proved that clothianidin from seed-treatments had contaminated honey, nectar, and pollen in the beehive, meaning bees can be exposed to clothianidin through these contaminated food sources. "Data Evaluation Record for honey bee field testing for pollinators." Reviewed by EPA: CE Padova, 18 September 2007; TS Myers, 26 September 2007; A Pease, 22 December 2010; T Steeger, 22 December 2010. http://www.epa.gov/pesticides/chemical/foia/cleared-reviews/reviews/044309/044309-090201-113501-079801-2010-12-22a.pdf (accessed September 8, 2011).

20 U.S. Environmental Protection Agency, *Conditional Registration*, September 25, 2012, http://www.epa.gov/pesticides/regulating/conditional-registration.html.

21 U.S. Environmental Protection Agency, *Conditional Registration—Issues with Tracking Conditional Registrations*, April 25, 2011, http://www.epa.gov/pesticides/regulating/conditionalregistration.html#issues (accessed September 8, 2011).