

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

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2011

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Dear Sir or Madam:

Thank you for your December 8, 2010, letter to Environmental Protection Agency (EPA) Administrator Lisa P. Jackson concerning the insecticide clothianidin. Since EPA's

Office of Chemical Safety and Pollution Prevention's Office of Pesticide Programs is responsible for the regulation of pesticides in the United States; I appreciate the opportunity to provide a detailed response to your concerns. I want you to know that EPA continues to advance its regulatory and scientific approaches to ensure honey bees and other pollinators are protected, and if scientific information shows a particular pesticide is posing unreasonable risk to pollinators, we stand ready to take the necessary regulatory action.

Clothianidin was originally evaluated for registration through a North American Free Trade Agreement (NAFTA) Joint Review with Canada and was identified as an alternative to the organophosphate insecticides, a class of insecticides that is generally very highly acutely toxic to bees and, unlike clothianidin, also very highly acutely toxic to humans and wildlife.

During the clothianidin registration process, hundreds of studies were reviewed and evaluated. When EPA granted the initial registration for clothianidin seed treatment uses in 2003, the Agency determined that the uses met the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) risk benefit standard for registration.

*If this is true, then why was clothianidin released to the market under a “conditional” registration in 2003 rather than full registration? EPA’s own documents clearly show that there were serious concerns, serious enough that EPA scientists said the life cycle study should be completed before registration, and the “condition” of conditional registration was the completion of the life cycle study by the end of the first growing season. It was not completed until 4 full growing seasons has passed. Anyone can see that by looking at the EPA memos. Do they think we can’t read? Or just that we can’t think?*

*“Hundreds of studies...”? Just send us a list of the first 200.*

Your letter refers to the "imminent hazard" you believe to be posed by clothianidin and urges the Agency to issue a "stop use order" to address the situation. Let me clarify how a stop sale, use and removal order operates. The Agency is authorized to issue a stop sale, use, and removal order under section 13 of FIFRA in response to a violation of FIFRA or after a pesticide has been cancelled or suspended. 7 U.S.C. ~ 136k(a). Since clothianidin has not been cancelled or suspended and there has not been a violation of FIFRA, it is unclear what basis the Agency would have for issuing such an order.

*Is this a Catch 22 or what? We can’t stop the sale or use because it hasn’t been cancelled, and we aren’t going to cancel it. The basis for issuing such an order is that **clothianidin has failed to meet the requirements for registration**, independent of all this other gibberish.*

When an actual imminent hazard exists, the Agency may suspend the pesticide registration in accordance with the provisions of section 6(c) of FIFRA. 7 U.S.C. ~ 136a(c). To do so, however, the Agency needs to determine that such an imminent hazard exists based on reliable scientific information. Although your letter references EPA's November 2, 2010 memorandum regarding the reclassification of a clothianidin field study, and "the science that the agency has, [sic] and the independent literature," you provide no explanation, evidence, or data to support an Agency finding of imminent hazard.

*Once again, **clothianidin has failed to meet the requirements for registration**, this is a smoke screen, more gibberish, and one more bureaucratic dodge.*

Through this letter the Agency is seeking to set the record straight and resolve any confusion about the meaning of the reclassification of the clothianidin field study from acceptable to supplemental. The 2003 registration of clothianidin was conditionally granted based, among other things, on the submission of a field test for pollinators. The registrant addressed this requirement with the field study (MRID 46907801 and 46907802) that you reference in your December 8, 2010 letter. This study has undergone several reviews since its submission and initial evaluation in 2007. The study was originally classified as an acceptable study (that is, a study that fully satisfies a test guideline), but is now classified as a supplemental study (that is, a study that provides scientifically-sound information, but did not follow all protocols set forth in EPA test guideline).

*More bureaucratic evasion, truly Orwellian. This isn’t an attempt to set the record straight, but rather an attempt to confuse the issue and spin the record away from the truth. What “scientifically-sound” information can be drawn from the life cycle study? The study was a farce, go back and read it if you doubt that. Bayer tried to slide a bogus study by to get this product on the market, EPA bit, and they have been caught in their complicity and are now*

*trying to justify their action. They are an embarrassment, and if they truly believe that the life cycle study “provides scientifically- sound information” they should be removed from their jobs immediately.*

*Conservatively, the test plots represented .0008 of the bees’ forage area and yet the bees were still contaminated by this product. If the life cycle study shows anything at all, it is that clothianidin is far more pernicious than first thought, but this fact seems to escape the EPA managers, does it escape the scientists as well? I think not, but they are being muzzled and coerced.*

A modification in the Agency's assessment of this study is reflective of EPA's improved understanding of honey bee biology and the recognition in the scientific community of the challenges associated with field pollinator study designs. While elaborate field studies can be designed, there may be confounding factors which limit, but do not entirely discredit, the utility of a study. It is clear that field pollinator studies cannot be viewed in the same context as laboratory studies where experimental conditions can be strictly controlled. Recognizing the complexity of conducting and interpreting field studies, EPA has made the best use of existing data. Although deficiencies were noted in this specific pollinator field study, including some cross contamination between treated and nontreated (control) plots, there was useful information that has been used to better understand hive survival following exposure to clothianidin.

*Hogwash, More Animal Farm, More irrelevant evasion, or as one commercial beekeeper characterized it, “more bureaucratic babble”. Please share with the American people what the useful information was and how it helps us to “better understand hive survival following exposure to clothianidin.” These test colonies might just as well have been in my back yard or yours, three thousand miles away, for the “useful information” they provided.*

The Agency bases pesticide risk characterizations on the entire body of information submitted by the pesticide registrant and open scientific literature data. For clothianidin, the weight-of-evidence risk characterization was based on 34 studies and not on the findings of a single, specific field study. Therefore, the reevaluation of the study in question does not change the Agency's conclusion that the registered uses of clothianidin meet the FIFRA risk benefit standard for registration. Clothianidin generally poses less risk to agricultural workers and fish and wildlife when compared to the organophosphate insecticide alternatives. While the acute laboratory data show that clothianidin is toxic to honey bees, as are most insecticides, current labels for clothianidin products used as foliar treatments include bee hazard statements that prohibit applications when plants are flowering and bees are in the area. At this time, we are not aware of any data that reasonably demonstrates that bee colonies are subject to elevated losses due to chronic exposure to this pesticide. Based on EPA's thorough review of the scientific information, EPA does not intend at this time to initiate suspension or cancellation actions against the registered uses of clothianidin.

*More dodging to confuse the issue. Nobody has said anything about “foliar treatments”, we are talking about seed treatments which are systemic, they become part and parcel of the plant, but the EPA has conveniently side stepped this central question. But let’s talk about foliar treatments and the bee hazard statements since they bring the subject up. Enforcement is a sham, an illusion, there is little or no enforcement. Right here in Boulder County we had a spray incident with a non-systemic pesticide, (one of the foliar treatments they are talking about) in 2008 where we took our own samples and the pesticide level was several hundred times the LD50 for honeybees. The EPA is responsible for enforcement, but delegates that authority to the states, It took 5 weeks of constant prodding before the state would come up and take samples and even then the pesticide level was still several times the LD50. The outcome? The applicator was given a slap on the wrist, a \$400 fine with no admission of guilt and still complained about it. How many thousands or tens of thousands of dollars were lost by surrounding beekeepers and what damage was done to the environment by this outrageous level of overspraying? It happens all the time and is seldom challenged, and when it is, it gets the same evasion, doublespeak and non-performance you see in this letter. Enforcement? Hardly. And what purpose does the bee hazard warning on labels serve with systemic*

*pesticides. Are we expected to remove our bees from the area for the next 100 years?.*

*There is abundant science emerging which shows the extreme danger of clothianidin, both to the bees and the broader environment, contrary to what the EPA managers would like us to believe. In heavy soils the half life is 19 years. This means that it will take over 100 years to purge the soil of this pesticide, and it appears that minute amounts can produce profound effects. The simple fact, the fact which the EPA is so desperately trying to sweep under the rug, is that **clothianidin has failed to meet the requirements for registration**. If you went in to get a driver's license and flunked the driver's test, it wouldn't make any difference how you were dressed or whether you part your hair on the right or the left, you flunked the test. **Clothianidin has flunked the test, period**. Bayer and the EPA tried to get by with sleight of hand and they got caught. If you caught a child with their hand in the cookie jar and they tried to excuse it away it would be obvious and laughable. It is only a little less obvious here, even though every sentence has undoubtedly been carefully parsed by a team of lawyers.*

*With regard to risk, the solution may be worse than the problem, this is a little like being accosted by a mugger who informs you that you won't be shot or stabbed, you'll just be given the environmental equivalent of HIV...and we are supposed to be grateful, the grateful dead perhaps. What will we tell our children and grandchildren 10, 20, 30 years from now? Sorry kids, we were just too busy to hold these people accountable. Corn rootworms and corporate profits were more important than your well being and protection of the environment.*

We know that as science advances, EPA must vigilantly improve our scientific methods to ensure pollinators are protected. We are actively involved in on-going research that is addressing the potential role pesticides may play in the status of honey bees and native bees. EPA proposed a global workshop that was organized by the Society of Environmental Toxicology and Chemistry (SETAC) on January 16 - 21, 2011. This scientific meeting was held to address advances in study designs and improve risk assessment approaches for honey bees. We currently anticipate proposing a revised risk assessment process for pollinators to the FIFRA Scientific Advisory Panel in 2012 for independent external peer-review. It is our expectation that the open and public process to be used for developing these revised risk assessment methods will increase understanding and strengthen the scientific and regulatory processes for protecting honey bees and pollinators.

*Balderdash.*

Given the concern about the neonicotinoid class of pesticides and protection of bees, the Agency has also accelerated scheduling the comprehensive re-evaluation of these pesticides in the registration review program. EPA's registration review docket for clothianidin will open this year. We are coordinating re-evaluation of the neonicotinoid insecticides with California's Department of Pesticide Regulation and Canada's Pest Management Regulatory Authority.

*This should have been done in 2003, before this product was ever released to the market. Instead, we have been subjected to 8 growing seasons of uncontrolled environmental experimentation and it looks like we are going for number 9.*

I hope this response clarifies the issues raised in your letter of December 10, 2010. Our office looks forward to working with all interested stakeholders to ensure protection of honey bees from pesticides. If you have any further questions, please contact Kimberly Nesci at 703-308-8059.

Sincerely,

Steven P. Bradbury, Director Office of  
Pesticide Programs

cc: Kimberly Nesci, OPP