



BEYOND PESTICIDES

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March 6, 2009

Office of Pesticide Programs (OPP)
Regulatory Public Docket (7502P),
Environmental Protection Agency,
1200 Pennsylvania Ave., NW.,
Washington, DC 20460-0001

**Re: Pesticide Experimental Use Permit: Amendment/Extension Application. Docket Number:
EPA-HQ-OPP-2008-0941**

Dear Sir/Madam:

Please accept these comments in response to the Federal Registrar Notice: *Pesticide Experimental Use Permit: Receipt of Amendment/Extension Application* published February 4, 2009. Beyond Pesticides and its members would like to use this opportunity to again voice our opposition to the experimental use of the plant incorporated protectant (PIP) *Bacillus thuringiensis (Bt) Cry1Ac* protein. Thus, we do not support the extension of the experimental use permit (EUP) to authorize the program conducted by Monsanto to test Cry1Ac protein and corresponding genetic material in MON 87701 soybean.

Beyond Pesticides believes that the continued use of Cry1Ac in any circumstance will only serve to promote serious, yet understudied public and environmental health risks associated with genetically modified organisms (GMOs). Furthermore, this new technology should be subject to complete regulatory oversight, which so far has been inadequate despite the fact that many consumer goods contain GMOs. Evidence exists that implicates Cry1Ac and other modified *Bt* proteins with mammalian toxicity, adverse impacts on non-target organisms and environmental contamination that warrant a halt to issuing or extending experimental use permits or conditional registrations. Furthermore, concerns over insect resistance to *Bt* raises long term efficacy and economic issues for agriculture.

Potential Human Health Impacts Not Adequately Considered

There are not many studies investigating the impacts of genetically modified organisms on mammals or even humans. However, the few studies that have looked at the toxicity of *Bt* proteins have observed that Cry1Ac is a potent immunogen. Research by Moreno-Fierros et al.

(2000) reported that Cry1Ac is a systemic and mucosal immunogen and adjuvant, as potent as cholera toxin, enhancing serum and intestinal IgG antibody responses in laboratory mice.^{1,2} This is important because it has already been observed that *Bt* sprays led to allergic skin sensitization and induction of IgE and IgG antibodies in exposed farm workers.³ Bakke-McKellep et al. (2007) found that salmon fed genetically modified soy had higher head kidney lysozyme, indicating immunological stimulation.⁴ These results indicate that exposures to certain GMOs, like Cry1Ac, may induce allergic responses, especially in those sensitive to food allergens.⁵

Apart from immunologic responses, other studies have observed that GMOs may cause some common toxic effects such as hepatic, pancreatic, renal, or reproductive effects and may alter the hematological, biochemical parameters.⁶ World renowned geneticist and biophysicist, and co-founder of the International Science Panel on Genetic Modification, Dr. Mae-Wan Ho, has cited numerous observations on the adverse impacts of GMOs, including severe inflammation in the lungs in mice, liver and kidney toxicity, damage to the organ system of young rats fed GM potatoes, and severely stunted pups.^{7,8} Others have noted that GMOs, especially those containing the Cry1 gene, caused profound hypertrophic and hyperplastic changes in cells by binding to the gut epithelium in mice studies.⁹ A recent study reported that GM corn fed to mice significantly reduced their fertility over three to four breeding cycles within one generation.¹⁰ This study again serves to illustrate the long term consequences of GMOs. These preliminary studies indicate that not only is more research into the impacts of GMOs on human health needed, but that the agency must consider these data and take a precautionary approach to limit the indiscriminate pervasion of GMOs in the human food supply. In light of the 2000 recall of Starlink corn due to reports of allergic reactions and the public fear and outrage that followed, the agency should be more prudent about allowing inadequately tested genetically modified food crops to enter the food supply.

¹ Moreno-Fierros, L., García, N., Gutiérrez, R., López-Revilla, R., and Vázquez-Padrón, R.I. (2000) Intranasal, rectal and
² Vázquez-Padrón, R.I., Moreno-Fierros, L., Neri-Bazán, L., de la Riva, G.A., and López-Revilla, R. (1999) Intra-gastric and intraperitoneal administration of Cry1Ac protoxin from *Bacillus thuringiensis* induces systemic and mucosal antibody responses in mice. *Life Sciences* 64, 1897-1912.

³ Bernstein, I.L., Bernstein, J.A., Miller, M., Tierzieva, S., Bernstein, D.I., Lummus, Z., Selgrade, M.K., Doerfler, D.L., and Seligy, V.L. (1999) Immune responses in farm workers after exposure to *Bacillus thuringiensis* pesticides. *Environmental health perspectives* 107, 575-582.

⁴ Bakke-McKellep, A.M., Koppang, E.O., Gunnes, G., Sanden, M., Hemre, G.I., Landsverk, T., and Krogdahl, A. (2007) Histological, digestive, metabolic, hormonal and some immune factor responses in Atlantic salmon, *Salmo salar* L., fed genetically modified soybeans. *J. Fish Dis.* 30, 65-79.

⁵ Bernstein, J.A., Bernstein, I.L., Bucchini, L., Goldman, L.R., Hamilton, R.G., Lehrer, S., Rubin, C., and Sampson, H.A. (2003) Clinical and Laboratory Investigation of Allergy to Genetically Modified Foods. *Environmental health perspectives* 111, 1114-1121.

⁶ Dona, A., and Arvanitoyannis, I.S. (2009) Health Risks of Genetically Modified Foods. *Crit. Rev. Food Sci. Nutr.* 49, 164-175.

⁷ Ho, M.-W., Cummins, J., and Saunders, P. (2007) GM Food Nightmare Unfolding in the Regulatory Sham. *Microbial Ecology in Health and Disease* 19, 66-77.

⁸ Ho, M.-W. (2008) Ban GMOs Now. In: *Lecture from Traditional Seeds Our National Treasure And Heritage -Traditional and Organic Agriculture instead of GMO* Warsaw, Poland.

⁹ Pusztai, A., Bardocz, S., and Ewen, S. (2003) Chapter 16: Genetically Modified Foods: Potential Human Health Effects. *Food Safety: Contaminants and Toxins* by J P F D'Mello, Scottish Agricultural College, Edinburgh, UK, April 2003.

¹⁰ Velimirov, A, Binter C., Zentek C. 2008. Biological effects of transgenic maize NK603xMON810 fed in long term reproduction studies in mice. Austrian Ministry of Health, Families, and Youth

Non-Target Impacts and Environmental Contamination Cannot be Dismissed as Inconsequential

Bt incorporated plants harm butterflies, such as monarchs and the endangered Karner Blue butterfly. The agency does not have sufficient data to dismiss scientific findings that show migrating monarchs exposed to *Bt* pollen are at risk. The agency, similarly, does not have sufficient data to show that non-target species are not put at risk. A study conducted by Hellmich et al. (2001) investigated the sensitivity of the monarch butterfly to Cry proteins and found that the first instars (stage between molts) were sensitive to Cry1Ab and Cry1Ac proteins, with Cry1Ab having the most impact on the species.¹¹ Kim et al. (2008) also found that Cry1Ac lead to decreased survival rates and body weights among the non-target larvae of silkworms, *Bombyx mori*.¹² These studies support the notion that non-target organisms are indeed at risk from exposure to GM crops on agricultural fields and the environment. In light of these and similar studies, the agency must be proactive and definitive in looking at the short and long-term impacts on non-target species.

When pollen from GM crops drift away from the field of application and into the environment or to other non-GM crops, cross pollination can occur leading to crop contamination. Evidence suggests that GM corn plants can cross-pollinate non-GM corn plants up to and beyond a distance of 200 m.¹³ Cross-contamination and hybridization between GM crops and wild plant species are also of major concern. One example is the transfer of herbicide resistant genes from GM crops to weed species,^{14,15} leading to the growth of highly resistant “super-weeds.” It is unclear and difficult to predict how the genetically engineered genes will be expressed in a related wild species. Therefore, research is needed to determine the frequency, introgression rates and potential ecological impact resulting from contamination of non-GM plant species.¹⁶ This must be done before GMOs are released into the environment.

Lack of Regulatory and Enforcement Capability

¹¹ Hellmich, R.L., Siegfried, B.D., Sears, M.K., Stanley-Horn, D.E., Daniels, M.J., Mattila, H.R., Spencer, T., Bidne, K.G., and Lewis, L.C. (2001) Monarch larvae sensitivity to *Bacillus thuringiensis*- purified proteins and pollen. pp. 11925-11930.

¹² Kim, Y.H., Kim, H., Lee, S., and Lee, S.H. (2008) Effects of *Bt* transgenic Chinese cabbage pollen expressing *Bacillus thuringiensis* Cry1Ac toxin on the non-target insect *Bombyx mori* (Lepidoptera: Bombycidae) larvae. *Journal of Asia-Pacific Entomology* 11, 107-110.

¹³ Eastham, K., and Sweet, J. (2002) Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer. Assessing the Impact of GM Plants (AIGM) programme for the European Science Foundation and the European Environment Agency Environmental issue report.

¹⁴ Jack Brown, A.P.B. (1996) Gene transfer between canola (*Brassica napus L. and B. campestris L.*) and related weed species. *Annals of Applied Biology* 129, 513-522.

¹⁵ Snow, A.A., Andersen, B., Oslash, and Rørgensen, R.B. (1999) Costs of transgenic herbicide resistance introgressed from *Brassica napus* into weedy *B. rapa*. *Molecular Ecology* 8, 605-615.

¹⁶ Belchera, K., Nolana, J., and Phillips, P.W.B. (2005) Genetically modified crops and agricultural landscapes: spatial patterns of contamination *Ecological Economics* 53 387-401. Eastham, K., and Sweet, J. (2002) Genetically modified organisms (GMOs): The significance of gene flow through pollen transfer. Assessing the Impact of GM Plants (AIGM) programme for the European Science Foundation and the European Environment Agency Environmental issue report.

Comments submitted to the agency by 26 leading scientists at public research institutions charge that patent-holding companies, including Monsanto, Syngenta, and others, interfere with their genetic engineering (GE) research on crops. These scientists state,

“Technology/stewardship agreements required for the purchase of genetically modified seed explicitly prohibit research. These agreements inhibit public scientists from pursuing their mandated role on behalf of the public good unless the research is approved by industry. As a result of restricted access, no truly independent research can be legally conducted on many critical questions regarding the technology, its performance, its management implications, IRM, and its interactions with insect biology. Consequently, data flowing to an EPA Scientific Advisory Panel from the public sector is unduly limited.”¹⁷

Stewardship agreements, which are intended to ensure that farmers honor the companies’ patent rights, do not allow planting GE crops for research. Few researchers conduct GE studies because of limitations and legal difficulties that may result. Those that go up against these corporations run the risk of being “blacklisted.”

Data submitted to EPA for regulatory purposes are mainly from industry stakeholders. The agency has a history of being unduly influenced by industry data, leading to skewed and flawed risk assessments. The agency must support and consider independent studies, some of which have shown that GMOs are associated with non-target impacts, short and long-term allergenicity, reproductive abnormalities and organ toxicity, instead of relying on industry sponsored data. Long-term studies are especially needed to test for harm from long-term consumption of GM foods. In making these considerations, the agency would assure that the integrity of the risk assessment process is improved.

When it comes to enforcement, EPA relies on a broken pesticide enforcement system. Compliance with label restrictions is very low and the agency is aware of this. The agency does not have an enforcement plan that will ensure compliance with conditions, mitigation measures or restrictions for any GM program, EUPs or product labels. This, coupled with the fact that there are no labeling requirements to identify GM foods, which takes away consumers’ a right to choose, makes it difficult to trace the impacts of GM products. Knowing that the agency does not have jurisdiction over many food products, EPA must work proactively with the Food and Drug Administration, the United States Department of Agriculture and others to ensure that the public health is protected.

¹⁷ Comments for “Evaluation of the Resistance Risks from Using a Seed Mix Refuge with Pioneer’s Optimum AcreMax 1 Corn Rootworm-Protected Corn”- FIFRA Scientific Advisory Panel; Notice of Public Meeting [EPA-HQ-OPP-2008-0836-0001](https://www.epa.gov/pesticides/OPP-2008-0836-0001) Available at <http://www.regulations.gov/fdmspublic/component/main?main=DocumentDetail&o=090000648084de39>

Legal Action Should Limit EPA’s Authority to Extend the Permit At This Time and Supports the Need for a Moratorium

In September 2008, the U.S. Court of Appeals for the Ninth Circuit, (*Geertson Seed Farms, et al. v. Johanns*) upheld a nationwide ban on the planting of GE “Roundup Ready” alfalfa pending a full Environmental Impact Statement (EIS). The Court determined that the planting of genetically modified alfalfa can result in potentially irreversible harm to organic and conventional varieties of crops, damage to the environment, and economic harm to farmers. The decision upholds U.S. District Court Judge Charles Breyer’s May 2007 ruling, in which he found that USDA failed to address concerns that Roundup Ready alfalfa will contaminate conventional and organic alfalfa. Judge Breyer specifically noted that Monsanto’s fear of lost sales “does not outweigh the potential irreparable damage to the environment.” Judge Schroeder’s decision affirms that USDA violated national environmental laws by approving GE alfalfa without a full Environmental Impact Statement. It also affirms that USDA failed to address the problem of Roundup-resistant superweeds that could follow commercial planting of GE alfalfa.

In light of this decision, EPA should establish a moratorium on the issue of experimental use permits and other registrations. The agency has a legal responsibility to meet the standards of the National Environmental Policy Act (NEPA) in evaluating the full impact of potentially registered products before allowing their proliferation into the environment. While the registration process under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) establishes important barriers to product use before allowing products into the field, which the agency has not met in this case, it is also critical that the agency consider questions of secondary impacts of its registered product under FIFRA and other environmental laws.

Conclusion

When genetically engineered (GE) food products were commercially developed in the 1990’s, they were sold to the public as a technology that, among other things, would reduce pesticide use. In reality, it has done just the opposite. According to a 2007 study published in the journal *Science*, 80 percent of the GE crops planted in the U.S. are modified to be resistant to herbicides. The second most common form of genetic modification incorporates the natural insecticide *Bacillus thuringiensis* (*Bt*) into the crop, and leads to *Bt*-resistance. Since 1996, the planting of GE crops has increased exponentially. According to the USDA’s National Agricultural Statistics Service (NASS), biotechnology plantings as a percentage of total crop plantings in the U.S. are 46 percent for corn, 76 percent for cotton, and 85 percent for soybeans. The Center for Food Safety estimates that nearly 75 percent of processed foods on supermarket shelves –from soda to soup, crackers to condiments—contain genetically engineered ingredients, which are linked to higher risks of toxicity, allergenicity, antibiotic resistance, immune-suppression and

cancer. Genetic engineering also poses a problem for those who wish to avoid these crops, including organic and non-GE conventional farmers whose crops are routinely contaminated with drifting GE pollen.

Beyond Pesticides does not support the extension of the experimental use permit (EUP) to authorize the program conducted by Monsanto to test Cry1Ac protein. Experimental use of Cry1Ac on over 1000 acres of land should not be permitted given that the protein has been associated with adverse impacts on non-target species. Cry1Ac has also been observed to induce allergic responses in humans and mammalian species, among other adverse effects mentioned above. Monsanto, and by extension EPA, has allowed this genetically modified material to enter the environment in order to conduct tests. Beyond Pesticides is of the opinion that tests should be conducted and assessed *before* such a potentially damaging material is allowed to enter the environment. In light of the 2008 court ruling in *Geertson Seed Farms, et al. v. Johanns*, EPA should establish a moratorium on the issuance on GM permits, registrations and products until it evaluates and establishes basic guidelines and thresholds for GMOs in order to meet the standards and statues pertaining to U.S. environmental laws.

Long-term human health impacts of GMOs, like Cry1Ac-crops, are not fully considered partly because independent studies needed to fairly assess the fate and effect of this new technology are few due to industry pressure and monopoly. Currently, the agency does not have sufficient data to show that GMOs pose no unreasonable risk. Until then, the agency must put the health of public and the environment first and limit the environmental release of GMOs.

Thank you for your consideration of our comments.

Sincerely,

Jay Feldman
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Beyond Pesticides

Nichelle Harriott
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Beyond Pesticides