THE CENTER FOR FOOD SAFETY

March 9, 2007

Docket No. APHIS-2006-0157
Regulatory Analysis and Development
PPD, APHIS, Station 3A-03.8, 4700
River Road Unit 118, Riverdale MD 20737-1238

Re: Revised and Expanded Comments on Environmental Assessment for Determination of Nonregulated Status for MIR604 Corn Genetically Engineered For Insect Resistance (replacing comments submitted on Feb. 9, 2007)

The Center for Food Safety submits these expanded and revised comments on the draft environmental assessment, Docket No. APHIS-2006-0157, concerning the inadequate Environmental Assessment (EA) for Determination of Nonregulated Status for Corn Genetically Engineered for Insect Resistance (*Bacillus thuringiensis* (Bt) Corn, transformation event MIR604),[1] and the Syngenta petition for deregulation.[2] Since submission of our original comments on February 9, 2007, before extension of the comment deadline to March 9, 2007, we have had greater opportunity to analyze the available evidence and therefore request that these comments be accepted in lieu of our original February 9, 2007 submission.

APHIS conducted inadequate environmental review by failing to consider the potential for significant environmental impacts associated with Syngenta's MIR604 corn, and by impermissibly deferring consideration of potential adverse impacts of MIR604 corn and its insecticidal protein on the environment and food safety to the EPA and FDA. Furthermore, APHIS prepared its Environmental Assessment without consulting, much less discussing, the testimony of independent experts that in numerous respects challenges the conclusions of APHIS's EA. These independent experts were expressly convened by USDA's sister agency, the U.S. Environmental Protection Agency (EPA), under the auspices of a FIFRA Scientific Advisory Panel (SAP) to consider and review human health and environmental issues associated with MIR604 and its mCry3A insecticidal protein. This SAP met on March 14 and 15, 2006, and issued its extensive

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[1] Environmental Assessment on Syngenta "Petition for Determination of Non-regulated Status," available at http://www.aphis.usda.gov/brs/aphisdocs/04_36201p_pea.pdf, (last visited February 8,2007) (Hereinafter (EA).

[2] Syngenta Petition for the Determination of Non-Regulated Status, Corn Rootworm Protected Transformation Event MIR604 (Revised) (hereinafter "SYNGENTA PETITION"), available at http://www.aphis.usda.gov/brs/aphisdocs/04_36201p.pdf (last visited February 8, 2007).

report on June 1, 2006.[3] This report was available to APHIS for more than seven months before it issued its EA for public comment on January 10, 2007; APHIS was aware of the existence of this report (EA, p. 3), but chose not to consult it.

These comments request that APHIS prepare an Environmental Impact Statement (EIS) to fully analyze the environmental and public health affects of the deregulation decision. CFS is a non-profit membership organization that works to protect human health and the environment by curbing the proliferation of harmful food production technologies and by promoting organic and other forms of sustainable agriculture.

The Center for Food Safety believes that the current U.S. regulatory structure does not provide adequate risk assessment of either human or environmental safety of genetically engineered (GE) crops, and therefore no GE crops should be commercialized until U.S. regulations can assure that all GE crops are safe. Short of such a blanket prohibition on GE crop commercialization, the deregulation and commercialization of this Bt Corn (transformation event MIR604), requires the preparation of an EIS under the National Environmental Policy Act ("NEPA"), because the EA contains unanswered or inadequately answered safety questions. Specifically, CFS requests that APHIS institute a moratorium on the commercial introduction, dissemination, interstate movement or conveyance of genetically engineered Bt Corn, transformation event MIR604, including but not limited to all food products containing any ingredients or material derived from this genetically engineered corn, until the USDA, as mandated under §102 of NEPA, fully evaluates the environmental, human health and socio-economic impacts caused by the commercialization of MIR604. Such action and analysis should include completion of an environmental impact statement analyzing the effects on the human environment resulting from any USDA actions deregulating (or other action allowing commercial distribution, sale and planting) MIR604.

Genetic engineering is a novel technology that fundamentally alters agriculture, our food supply, and the environment. Biotechnologists now are able to take genetic material from one organism and insert it into the permanent code of another. Among these novel creations are varieties of corn that have been genetically engineered to express a variety of insecticidal proteins similar to those generated in soil organisms of the species *Bacillus thuringiensis* (Bt), destined for widespread cropping to be sold as human food and animal feed. Syngenta has petitioned USDA to deregulate a new genetically engineered Bt corn variety (MIR604) with novel characteristics. Scientific research indicates that introducing genetically engineered MIR604 corn into the environment poses potential adverse human health and ecological threats, particularly if released at a commercial scale.

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[3] United States Environmental Protection Agency, "A Set of Scientific Issues Being Considered by the Environmental Protection Agency Regarding Event MIR604 Modifie5d Cry3A Protein Bt Corn – Plant Incorporated Protectant," Minutes of a Meeting of the FIFRA Scientific Advisory Panel, held March 14-15, 2006, June 1, 2006, available at http://www.epa.gov/scipoly/sap/meetings/2006/march/finalmeetingminutes6_1_2006.pdf, last visited February 8, 2007, incorporated by reference.

In addition, there are significant unanswered questions regarding the potential impacts of MIR604 corn and its mCry3A insecticidal protein on non-target organisms, including at least one endangered species, as well as human health effects on persons consuming corn products containing mCry3A.

NEPA Requires APHIS to Review the Impacts to Environment, Human Health and Economy that Will Result From the Commercialization of Genetically Engineered Bt Corn.

The National Environmental Policy Act (NEPA) is the "basic national charter for protection for the environment."[4] NEPA is intended to "promote efforts which will prevent or eliminate damage to the environment and biosphere and stimulate the health and welfare of man."[5] The duties under this section are not "inherently flexible."[6] The purpose behind NEPA is to "insure that environmental information is available to public officials and citizens before decisions are made and before actions are taken."[7]

Recognizing the affects of new technologies on the environment, Congress explicitly stated in NEPA that "new and expanding technological advances" are activities that could threaten the environment.[8] In the legislative history, Congress expressed its concern with "[a] growing technological power … far outstripping man's capacity to understand and ability to control its impact on the environment."[9] Thus, in order to understand and control the effects of new technologies, Congress required federal agencies to consider their environmental effects by prescribing the requirements of NEPA. In addition to environmental concerns, the proposed action's possible direct, indirect, and cumulative impacts on public health must be reviewed.[10]

As mandated by Congress, USDA must comply with NEPA before it attempts to deregulate and allow the commercialization of genetically engineered Bt corn. USDA is the lead federal agency designated to undertake NEPA analysis for the commercialization of genetically engineered plant varieties. USDA's decision whether to deregulate a genetically engineered Bt corn variety is a major federal action that may significantly affect the environment. The commercial planting of genetically engineered Bt corn could

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[4] 40 C.F.R. § 1500.1.

[5] 42 U.S.C. § 4321.

[6] Calvert Cliffs Coordinating Comm. Inc. v. U.S. Atomic Energy Comm'n, 449 F.2d 1109 (D.C. Cir. 1971).

[7] 40 C.F.R. § 1500.1(b),(c).

[8] 42 U.S.C. § 4331(a).

[9] Found. on Economic Trends v. Heckler, 756 F.2d 143, 147 (D.C. Cir. 1985) (quoting S. Rep. No. 91-296 (1969)).

[10] 40 C.F.R. § 1508.8(b); Baltimore Gas & Elec. Co. v. NRDC, 462 U.S. 87, 106 (1983)(explaining that "NEPA requires an EIS to disclose the significant health, socioeconomic, and cumulative consequences of the environmental impact of a proposed action.").

impact a vast number of acres and will have significant impacts on the environment, including impacts to human health and safety and cumulative impacts.[11]

The CEQ regulations list factors that determine whether a federal action, such as deregulating genetically engineered Bt corn is "significant." The CEQ regulations define the term 'significantly' for purposes of NEPA as requiring analysis of both the 'context' and the 'intensity' of the action."[12] Context is the scope of the agency action.[13] Intensity "refers to the severity of the impact" and is defined by the factors in 40 C.F.R. section 1508.27(b). Courts rely on these factors to determine "significance." Even meeting just one of the factors in 1508.27(b) may require the preparation of an EIS.[14]

The USDA specifically adopted these CEQ regulations in relation to APHIS' review of genetically engineered crop.[15] The factors include:

> - the degree to which the proposed action affects public health or safety;[16]
>
> - the degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks;[17]
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> - Whether the action is related to other actions with individually insignificant but cumulatively significant impacts.[18]

As discussed herein, the commercial introduction of genetically engineered Bt corn poses novel human health threats, in particular antibiotic resistance that constitutes unique environmental impacts, and impacts to human health and safety. Following is a description of some of the impacts that the USDA must evaluate.

A. The EA Is Defective Because APHIS Improperly Relied on EPA's and FDA's Regulations Instead of Conducting an Independent NEPA Evaluation of the Environmental Impacts of Bt Corn

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[11] 40 Fed. Reg. §§ 1508.27(b)(2), (5), (7)

[12] Anderson v. Evans, 371 F.3d 475, 487 (9th Cir. 2004).

[13] National Parks & Conservation Ass'n v. Babbitt, 241 F.3d 722, 731 (9th Cir. 2001).

[14] Ocean Advocates v. U.S. Army Corps of Engineers, 402 F.3d at 865 (9th Cir. 2005) (citing Nat'l Parks, 241 F.3d at 731).

[15] 7 C.F.R. § 372.4

[16] 40 Fed. Reg. § 1508.27(b)(2)

[17] 40 Fed. Reg. § 1508.27(b)(5)

[18] 40 Fed. Reg. § 1508.27(b)(7)

In its EA, APHIS impermissibly relied on EPA's Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) (7 U.S.C. 136 *et seq*.) and Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 301 *et seq*.) regulations and failed to conduct an independent NEPA evaluation of the environmental effects associated with the deregulation.[19] APHIS cannot solely rely on another agency's evaluation of environmental effects under a separate statute to adequately fulfill its own NEPA obligations.[20] In *Save Our Ecosystems*, the Ninth Circuit held that the Forest Service could not rely on EPA's registration process for herbicides under FIFRA to address environmental impacts pursuant to NEPA.[21]

In this case, APHIS violated NEPA because it improperly relied on EPA's temporary[22] exemption from the requirement of a tolerance for the mCry3A insecticide as established by EPA under the FFDCA.[23] APHIS failed to discuss the environmental impacts of increased pesticide residues associated with Bt corn, and instead wholly relied on EPA's temporary exemption. Thus, as in *Save Our Ecosystems*, where the agency improperly relied solely on EPA's FIFRA compliance, APHIS cannot here rely soley on EPA's FFDCA compliance to meet its own NEPA obligations.

APHIS also improperly relied on FDA's process under the Federal Food, Drug, and Cosmetics Act ("FFDCA") to justify its EA without addressing any human food safety issues whatsoever. APHIS deferred to FDA on food related issues completely.[24] However, APHIS failed to even look at the FDA data and FDA's consultation with respect to this crop has not even been completed. There are many food issues, however, that need to be addressed in an EIS, namely the potential for allergies, antibiotic resistance, immuno-supepression, cancer, and loss of nutrition.[25] APHIS cannot abdicate its own NEPA responsibilities with such improper reliance.[26] The need to examine the potential for allergenic or other human health impacts is only increased by the EPA Scientific Advisory Panel's identification of grave inadequacies in Syngenta's studies in this area. Studies of mCry3A's potential mammalian (including human) toxicity were flawed in a number of ways, leading some Scientific Advisory Panel members to determine that "no conclusion on safety could be derived from the data and that much

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[19] EA at 3.

[20] *Save Our Ecosystems v. Clark*, 747 F.2d 1240, 1248 (9th Cir. 1984); *Or. Envtl. Council v. Kunzman*, 714 F.2d 901, 905 (9th Cir. 1983).

[21] 747 F.2d at 1248 (explaining that FIFRA only requires a cost-benefit analysis and holding that FIFRA "does not require or even contemplate the same examination that the [agency] is required to undertake under NEPA"); s*ee also Wash. Toxics Coal. v. U.S. EPA*, 413 F. 3d 1024, 1032 (9th Cir. 2005).

[22] It is important to note that EPA has granted only a temporary, not a ***permanent,*** exemption from the requirement of a tolerance for mCry3A. The EPA typically grants temporary tolerance exemptions during the field testing of a pesticide-producing crop, and requires much less data for these than for permanent tolerance exemptions based on the presumably lesser environmental risk of the smaller scale of field trials versus commercial-scale plantings.

[23] Id.

[24] Id.

[25] "The Hidden Health Hazards of Genetically Engineered Foods," Food Safety Review, Spring 2000, vol. 1 (Attachment __)

[26] *See Save Our Ecosystems*, 747 F.2d at 1249.

more information is needed about acute effects and potential effects on children's growth and development." In addition, "[a]t least three Panel members expressed concern regarding the adequacy of the scientific basis supporting a permanent exemption from the requirement for a tolerance [for mCry3A]." With respect to allergenicity, Panel members noted that "non-oral routes of exposure were not explored and … true allergenicity studies were not performed." Some Panel members requested "more rigorous allergenic testing/monitoring of mCry3A among workers or consumers of products generated from this type of corn" (p. 10).

APHIS' reliance on FDA is more problematic given the limited nature of FDA's process. FDA created a voluntary consultation process in which FDA receives from biotechnology companies a bare summary of food safety and nutritional data regarding its proposed crop. The agency does not even make its own determinations of safety; rather, it merely states its understanding that a biotechnology company has concluded the crop is safe, and that further FDA approval or premarket review is not required.[27] This cursory process in no way resembles or can be considered sufficiently equivalent in scope nor depth to the searching, "hard look" required of APHIS by NEPA. Thus, APHIS must prepare an EIS to address the pesticide and food issues that it impermissibly deferred to the other agencies.

B. The EA is Defective Because APHIS Failed to Take the "Hard Look" Demanded by NEPA

In its review of potential human health and environmental impacts of MIR604 corn and its incorporated mCry3A insecticidal protein, the EPA's Scientific Advisory Panel (SAP) considered much the same data as did APHIS in its review of Syngenta's petition. Yet the assessments of the SAP and APHIS were radically different. APHIS merely reiterated Syngenta's conclusions without analysis, reservation, or comment, while the SAP found Syngenta's science to be shoddy and in many cases of little or no value for risk assessment purposes. As noted above, APHIS failed to consider or discuss even a single point raised by the independent experts of the SAP. Below, we discuss APHIS's reiteration of Syngenta's conclusions versus the critical assessment conducted by the SAP. All SAP references below refer to the document cited in footnote 3 above.

1. Potential impacts on non-target organisms, including beneficial organisms

APHIS reiterates the data, assessments and conclusions in Syngenta's petition, offering no independent analysis. In contrast, the SAP finds numerous flaws that invalidate the Syngenta/APHIS analysis. For instance, Syngenta/APHIS maintain that: "Acute dietary toxicity studies of beneficial arthropods were conducted in laboratory tests and no adverse effects were observed at levels 10.6 to 36 times the estimated environmental exposure (EEC) calculated using estimates of corn consumption for each organism (revised petition, Table 19, p. 87)." If APHIS had referred to the SAP's report, it would have seen that the mCry3A toxin levels to which the beneficial arthropods were actually exposed in Syngenta's tests were much lower than stated by

[27] See 57 Fed. Reg. 22984 (FDA's Policy on Foods Derived from New Plant Varities).

Syngenta/APHIS, thanks to serious methodological errors on the part of Syngenta. According to the SAP, the test exposure levels ranged from 1.1 (one point one, not 11) to 15 times the EEC for these five species of arthropods rather than 10.6 to 26 times (SAP, Table 1, p. 16). EPA guidelines call for tests of this sort to be carried out at 10 times the EEC to provide a margin of safety, and the test for only one of these five organisms (*Apis*, or honeybees) meets this standard when the values are corrected. Some Panel members considered this error serious enough to invalidate Syngenta's tests and the Syngenta/APHIS conclusion that the *Orius*, *Poecilus*, *Aleocharia* and *Coccinella* arthropods are not harmed by the toxin in MIR604 corn at levels likely to be encountered in the environment (SAP, p. 16), particularly the test on *Poecilus* (ground beetle) (SAP, p. 9).

In addition to these serious test dosage errors, there were also numerous deficiencies in the experimental design and statistical interpretation of Syngenta's tests. The SAP found that "improper or inadequate replication weakened the validity" of mCry3A acute toxicity tests conducted on rainbow trout, mouse and bobwhite quail (SAP, p. 9). The number of individuals tested was often too low to achieve statistical significance, for instance, only 4 honeybees (N = 4) in the *Apis* toxicity test (SAP, p. 19). Altogether, statistical design, analysis and reporting flaws invalidated 12 of 19 of Syngenta's tests/analyses with respect to non-target organism toxicity testing and related studies (SAP, far right column of Table 2, p. 18). In contrast, APHIS merely reiterates Syngenta's conclusion that no harm is to be expected to non-target organisms.

The SAP sharply criticized the complete disregard of signs of sub-lethal toxicity to test animals fed MIR604 corn. For instance, the SAP noted that rainbow trout (*Oncorhyncus*) fed MIR604 were in general shorter than those fed a control diet (SAP, p. 19); in addition, "observations of discoloration, sounding and surfacing … while not causing increased lab mortality, may significantly increase predation rates in the field" (SAP, p. 21). The SAP also noted greater variance in the size and weight of rainbow trout fed MIR604 versus controls, which "could be the result of stress due to the PIP [plant-incorporated protectant, or mCry3A] acting on genetic variability among the test subjects" (SAP, p. 19). Female bobwhite quail (*Colinus*) fed MIR604 corn exhibited a greater change in weight than controls, while male quail exhibited lesser weight change than controls, a sex-dependent effect that went unreported by Syngenta. In the case of both quail and trout, several SAP members found these signs of sub-lethal effects serious enough to "trigger subsequent hazard assessments" (SAP, p. 21), which have not been conducted. In contrast, APHIS accepted Syngenta's interpretation of its tests without comment.

The SAP also noted that neither Syngenta nor the EPA considered the potential for components of feed formulations to interact with, and potentially increase the uptake of, the mCry3A toxin in MIR604 (SAP, p. 22). APHIS says nothing about this issue in its EA.

The SAP advises that marine and estuarine organisms may be impacted by mCry3A-containing runoff water in areas "where large acreages of corn are grown in coastal plain habitats that discharge directly into receiving streams" (SAP, p. 22). Syngenta submitted no mCry3A toxicity tests on marine or estuarine organisms. APHIS does not address the issue in its EA.

2. Endangered species

The Hungerford's crawling water beetle (*Brychius hungerfordi*) is found in corn production areas of Michigan's northern Lower Peninsula where they could encounter corn crop residues, including MIR604 corn residues. Several SAP members strongly recommended assessment of the potential impact of MIR604 corn on this endangered beetle species. APHIS does not address the Hungerford's crawling water beetle in its EA (EA, pp. 11-12). APHIS states in its EA that it "has thoroughly examined all threatened and endangered coloepterans that occur in counties where corn is grown, and determined that the breeding habitat of coloepterans does put them in proximity to corn fields." APHIS goes on to speculate that despite this proximity to corn fields, there will be no exposure of endangered beetles to MIR604 corn, without reference to any scientific study or other source of information to support this speculation.

3. Soil degradation and earthworm studies

Several studies of other types of Bt corn have indicated that the insecticidal Bt toxin (e.g. Cry1Ab) leaks from the roots of the corn, persists in the soil by binding to clay particles in the soil, and that Bt corn residues decompose more slowly than non-Bt corn residues (cited in SAP, p. 23). These results suggest the need for careful analysis of the soil fate of any Bt insecticidal protein, given the potential for buildup of such toxins in the soil and the thereby increased potential for harm to the many soil organisms which have ***not*** undergone testing for potential toxicity of the pertinent Bt protein, including mCry3A.

Syngenta's testing in this regard was grossly inadequate on several counts. First, the company provided the results of only a single study on a single soil type, despite the huge variation in soil composition in the many regions of the U.S. where corn is grown, and the known impact soil composition can have on Bt protein persistance in soils. Secondly, and incredibly, the company employed bacterial surrogate mCry3A protein for this test rather than actual MIR604 crop residues containing the mCry3A protein as expressed in corn.

The SAP provides nearly 3 pages of comments on this inadequate study (SAP, pp. 23-26), calling for tests with MIR604 corn residues rather than bacterial surrogate mCry3A, and additional tests on five other soil types that predominate in corn-growing areas, among other recommendations. The SAP also criticized the single test that Syngenta did conduct on numerous counts for poor methodology and failure to report basic data. The SAP concludes that this "soil dissipation" study "should be excluded from consideration in ecological hazard/risk assessment … since [its] study design and data reporting did not meet basic Agency [EPA] standards" (SAP, p. 9).

In contrast, APHIS devotes all of three sentences to this study (EA, p. 12, "Environmental fate in soil"), simply restating Syngenta's results without reservation, analysis or comment of any sort.

The SAP (p. 14) notes numerous flaws that invalidate Syngenta's test for potential toxicity of mCry3A to the earthworm (*Eisenia*), including a gross overestimate of the amount of mCry3A toxin the earthworms were actually exposed to in the test due to several serious methodological errors by Syngenta.

While Syngenta reported that earthworms were tested at 46 times the expected environmental exposure level (ECC), the SAP's corrected value was 6.2 times the ECC, or over 7-fold less. This falls below the EPA's 10 x EEC testing standard, and is one of several reasons that the SAP recommended that this study, too, be "excluded from consideration in ecological hazard/risk assessment" (SAP, p. 9).

In contrast, APHIS merely reiterates Syngenta's interpretation of this deeply flawed test, without reservation, analysis, or comment (EA, p. 11).

4. Use of Bacterial Surrogate for Testing in Lieu of MIR604-Expressed mCry3A

The SAP devoted pp. 29-35 of its report (summarized on p. 10) to a discussion of the differences between bacterial surrogate mCry3A used in the great majority of Syngenta's tests and MIR604 corn-expressed mCry3A. Major differences were found between the two such that "it was not certain that the different forms of the mCry3A produced in corn versus *E. coli* could be considered substantially equivalent for the purpose of non-target invertebrate studies" (SAP, p. 10).

Two forms of corn-expressed mCry3A were detected – of molecular weights of 67 kDa and 55 kDa. The SAP thinks it is likely that the 55 kDa fragment is an active breakdown product of the 67 kDa protein, but noted that: "No data were presented suggesting that this break down product was characterized in any way … The Panel believes that this form should be characterized to insure that it is, in fact, a simple breakdown product and that it has not been modified in any other way. Without more information on this protein, it is difficult to conclude that the [bacterial surrogate] test material was fully equivalent to the plant material" (SAP, p. 33). Supporting the need for full characterization of this protein, the SAP noted that: "…even single amino acid substitutions in a protein can have major deleterious effects on occasion (for example, the change in sickle cell hemoglobin and other single site mutations in a variety of genetic diseases)" (pp. 31-32).

In contrast, the surrogate mCry3A protein produced in *E. coli* came in two forms: a 67.7 kDa short form (SF) and a 69.5 kDa long form (LA) in the ratio of 2 parts SF to 3 parts LF. Since neither of these forms is equivalent to the 55 kDa fragment that comprises roughly half of corn-expressed mCry3A: "there is reasonable cause not to consider these two forms of mCry3A [i.e. corn-expressed versus bacterial surrogate] substantially equivalent" (SAP, p. 33).

In short, the SAP concluded that the use of bacterial surrogate protein cast grave doubt on the validity of the non-target invertebrate studies; and one Panel member regarded the differences between bacterial surrogate and corn-expressed mCry3A, and the lack of data to further elucidate the differences, as sufficent grounds for rejecting the conclusions of mammalian toxicity and allergenicity studies carried out with bacterial surrogate (SAP, p. 34-35).

In contrast, APHIS states merely that: "Syngenta verified that the bacterially-produced mCry3A protein, as purified and prepared for these [non-target organism] studies, was similar in its biochemical properties (molecular weight, amino acid sequence and lack of glycosylation) and in biological activity

against WCRW [western corn rootworm] and thus was relevant to use as a test substance comparable to mCry3A as produced in line MIR604 corn." (EA, p. 10).

APHIS's statement is egregiously wrong on several counts. First, as noted above, the molecular weights of the two E. coli-produced forms of mCry3A (67 and 69.5 kDa) are roughly 23% greater than roughly half the mCry3A produced in corn (i.e. the 55 kDa form). A 23% difference in molecular weight is substantial, and controverts APHIS's assertion of "similarity" in molecular weight. Secondly, the SAP notes that corn-expressed mCry3A forms taken together are roughly twice as active against WCRW as the bacterial surrogate forms, due presumably to the greater lethality of the 55 kDa found in the corn but not bacterial forms of the protein (SAP, p. 32), directly controverting APHIS's assumption of "similar biological activity against WCRW." Thirdly, APHIS completely fails to even note the fact that both corn-produced mCry3A and bacterial surrogate mCry3A each come in two different forms, and that, for instance, the long form of corn-expressed mCry3A is "more than four-fold less active than the short form in at least one study with WCRW," and that "[t]his difference in activity causes difficulties in analysis of other test results for both the environmental and health effects studies" (SAP, p. 32).

These are just a few of many signs that APHIS is apparently unaware of basic biochemical features of the insecticidal proteins whose properties stand at the center of its environmental assessment, and of the bacterial surrogate versions that have been used in lieu of it for the great majority of Syngenta's testing.

5. Need for additional studies

According to the SAP, the EPA has requested Syngenta to provide "supplementary studies that will evaluate the persistence of mCry3A in the soil and the long range effects of cultivation of mCry3A on the invertebrate community structure in corn fields. This will facilitate identification of ***potential adverse effects which may result from long-term use of this product***." (SAP, p. 27, emphasis added). These studies – long-term field studies of ecosystem effects and long-term soil degradation field studies – are obviously of great relevance to APHIS's environmental assessment, all the more so because of the severe deficiencies in many aspects of Syngenta's testing. And the focus of these studies on discovering potential adverse impacts from ***long-term*** use of MIR604 are of special relevance to APHIS because a deregulation decision would be permanent, and would completely remove MIR604 from any further regulation by APHIS.

6. SAP's Summary Assessment of Syngenta's Studies

While we have covered many of the SAP's criticisms above, the following paragraph from the Panel's summary (p. 9) captures well the shoddy nature of Syngenta's science upon which APHIS relied so uncritically in writing its EA.

"Overall, the Panel found poor data quality and inadequate documentation in many aspects of the registration packet for mCry3A safety, from amino acid sequence reporting to documentation of natural versus plant incorporated protein homology to toxicity testing protocols. The errors or omissions in some studies

were of a nature and degree that many on the Panel believed they should be excluded from consideration in ecological hazard/risk assessment (in particular the earthworm, soil dissipation, and ground beetle studies) since their study designs and data reporting did not meet basic Agency standards. Omissions in several other studies reduced the certainty of estimates to the point where they may not be useful even in Tier 1 hazard assessments. In several instances the hazard quotients or safety factors computed were deemed by the Panel to be too low and/or unreliable. In others, specifically in the rainbow trout, mouse, and quail studies, the safety factors were sufficiently high; but improper or inadequate replication weakened the validity of all three tests and their conclusion of no acute mortality hazard."

7. Conclusion

In conclusion, we stress that APHIS did not take the "hard look" at Syngenta's petition that is required by NEPA. We have demonstrated this failure to take a hard look by comparing APHIS's EA to the EPA's SAP report. APHIS's EA, in at least the points discussed above under B1 to B6, ***merely reiterates*** the data, assessments and conclusions in Syngenta's petition, including material that is in error. The mere fact that APHIS chose to ***ignore*** the most relevant and well-credentialed independent assessment of Syngenta's data available to it is telling. It strongly suggests that APHIS did not want to address any critical analysis of Syngenta's petition that might complicate its predetermined goal of deregulation. We stress that environmental assessments have no meaning if undertaken as a mere formality to "rubber-stamp" a foregone conclusion – in this case, deregulation of MIR604.

C. The EA Is Defective Because it Failed to Analyze Cumulative Impacts

The EA is defective because it failed to analyze cumulative impacts whatsoever. A cumulative impacts analysis is required and it cannot be conclusory.[28] "A proper consideration of the cumulative impacts of a project requires some quantified or detailed information."[29] "[I]t must provide a useful analysis of the cumulative impacts of past, present and future projects."[30] The CEQ defines "cumulative impact" as "the impact on the environment which results from the incremental impact of the action when added to other past, present, and reasonably foreseeable future actions."[31]

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[28] 40 Fed. Reg. § 1508.27(b)(7); *Envtl. Prot. Info. Ctr. v. Blackwell*, 389 F.Supp.2d 1174, 1190 (N.D. Cal. 2004).

[29] *Klamath-Siskiyou Wildlands Center v. Bureau Of Land Mgmt*., 387 F.3d 989, 993 (9th Cir. 2004) (internal quotations omitted).

[30] Id. (internal quotations omitted).

[31] 40 C.F.R. § 1508.7.

Several Bt Corn varieties have been granted non-regulated status by the USDA and are currently cultivated on millions of acres across the United States.[32] The EA makes no mention of these past projects, or the cumulative environmental affects associated with this petitions' addition to the Bt corn supply. A cumulative effect can be expected due to the addition of yet another Bt corn variety, adding to the already developed resistance to Bt (an important organic alternative to chemical pesticides), adding to the problem of antibiotic resistance to clinically critical antibiotics, among other environmental impacts. This must be addressed in an EIS.[33]

CONCLUSION

For the reasons set forth below, APHIS should prepare an EIS to disclose and evaluate potentially significant effects that it has completely disregarded in the EA.

Sincerely,

Will Rostov, Senior Attorney
Kevin Golden, Staff Attorney
Bill Freese, Science Policy Analyst

[32] Petitions for Non-regulated Status Granted, APHIS, available at http://www.aphis.usda.gov/brs/not_reg.html, last visited February 8, 2007.

[33] 40 C.F.R. § 1508.7.