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Regulatory Analysis and Development
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Station 3A-03.8
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To whom it may concern:

The Center for Food Safety offers the following comments on USDA's preliminary environmental assessment of a field trial proposed by SemBioSys, Inc. for planting of up to 1,000 acres of safflower genetically engineered to produce a carp growth hormone in Washington State.

The Center for Food Safety is a national non-profit membership organization working to protect human health and the environment by curbing the use of harmful food production technologies and promoting organic and other forms of sustainable agriculture. CFS combines multiple tools and strategies in pursuing its goals, including litigation and legal petitions for rulemaking, legal support for various sustainable agriculture and food safety constituencies, as well as public education, grassroots organizing and media outreach. In addition to actively working on a myriad of human health and environmental issues regarding genetically engineered crops such as the safflower here, CFS also works on environmental and human health impacts associated with aquaculture and genetically engineered fish.

In the February 5, 2007 edition of the Federal Register, USDA announced a public comment period on its preliminary environmental assessment (EA) and decision to allow SemBioSys Genetics, Inc. to grow safflower genetically engineered to express carp growth hormone in Washington State this year.

Safflower is a food crop valued primarily for its oily seeds, which are used to produce edible oil for human consumption, birdseed, and as supplements for fish and animal feed.

SemBioSys' application

On September 5, 2006, SemBioSys submitted a permit application (06-250-02r) to USDA requesting approval to plant 1,000 acres of hormone-producing safflower in up to 10 different sites of 50-100 acres each in Washington state. The purpose of the 2007 planting is to obtain "a seed increase of material for future use as a supplement in aquaculture meal." (EA, p. 4).

This acreage in the requested permit represents a 50-fold increase over last year's 20-acre field trial in Washington, which was conducted under USDA permit 05-320-01r. If this year's permit is approved, the company could move into commercial production whenever it wishes.

SemBioSys engineered the safflower to produce a carp growth hormone in its seeds with the aim of selling the pharmaceutical seed meal to the aquaculture industry. The company plans to market the hormone-containing meal to treat diseases in farmed shrimp and promote growth of farmed fish.

Environmental Assessment: USDA's findings

The analysis in USDA's EA of SemBioSys' proposed pharma safflower production is designed to inform USDA as to whether or not a full environmental impact statement (EIS) is required under the National Environmental Policy Act (NEPA) and whether a permit should be issued under USDA's Plant Protection Act regulations.

NEPA

NEPA requires USDA to prepare an environmental impact statement (EIS) for major federal actions that significantly affect the quality of the human environment.[1] The EIS must "provide full and fair discussion of significant environmental impacts and [must] inform decisionmakers and the public of the reasonable alternatives which would avoid or minimize adverse impacts or enhance the quality of the human environment."[2] When an EIS is not categorically required, the department must prepare an environmental assessment (EA), which lays out the data and analysis determining whether the effect on the environment is significant enough to require an EIS. If an EA produces a finding of no significant impact, no EIS is required.[3]

NEPA regulations require the analysis of both direct and indirect, as well as cumulative, effects in NEPA documents, including EAs.[4] CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[5]

USDA's EA concludes that SemBioSys' proposed production poses no significant environmental impact and that "there are no applicable, extraordinary, or other reasonably foreseeable

[1] 42 U.S.C. § 4332(C).
[2] 40 C.F.R. § 1502.1.
[3] 40 CFR parts 1500-1508
[4] See 40 C.F.R. §§ 1508.8, .9, .13, .18.
[5] See 40 C.F.R. §§ 1508.8 & 1508.18.

circumstances under which significant environmental effects could occur given the protective and ameliorative measures specified [in the EA]."[6]

USDA regulations

Under the Plant Protection Act of 2002 and regulations governing GE organisms,[7] companies must secure permits to plant pharmaceutical-producing plants. Typically, the department's EAs on engineered crops include an analysis of the crop's plant pest and other environmental risks that underlie the determination of whether to grant or deny a permit.

In this case, USDA decided to issue a permit with supplemental conditions for the SemBioSys production "based on [the department's] scientific analysis of the permit application."[8] USDA made no determination on the likelihood that the escaped safflower genes or seed posed unacceptable or plant pest risks, but instead determined that imposition of the measures outlined in the supplemental permit conditions[9] would "prevent spread of the organism outside the field production area",[10] and "ensure no significant harm to the environment."[11]

Center for Food Safety's Conclusion and Recommendations

1. Inadequacies of USDA's Environmental Assessment

The SemBioSys EA fails to provide sufficient public evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact (FONSI). The public evidence it does provide does not support the conclusion that the impacts of planting hormone-containing safflower will be insignificant.

a. The EA fails to provide sufficient public evidence and analysis for determining whether to prepare an EIS or a finding of no significant impact.

Under NEPA, an agency must prepare a "public document … that … provide[s] sufficient evidence and analysis for determining whether to prepare an environmental impact statement or a finding of no significant impact."[12]

In this EA, however, USDA has withheld information from the public that appears to be critical to the conclusion that pharma safflower can be contained. That information is being kept from the public on the grounds that it is confidential business information (CBI).

USDA's finding of no significant impact rests on the department's certainty that the company can confine the pharma safflower to planting and other production sites. That certainty in turn depends

[6] EA, p 29
[7] 7 CFR part 340
[8] EA, p. 7
[9] EA, appendix VII
[10] EA, p 5
[11] EA, p 6
[12] 40 CFR part 1508.9

on the company's strict adherence to procedures and safeguards described in three documents:[13] the company's permit application, the company's standard operating procedures (SOPs),[14] and USDA's supplemental permit conditions.

However, USDA has withheld two of those documents—the permit application and the SOPs—from the public as CBI. Since these two documents are central to the EA's conclusion of no significant impact, the evidence contained therein must be made public. The withholding of these two key documents is at variance with USDA's conduct in similar cases in the past, when such information has been provided. It also conflicts with the recommendations for greater public transparency made by a National Academy of Sciences panel that reviewed USDA's performance at regulating GE crops.[15]

An EA such as this one that withholds key scientific information is legally inadequate and circumvent the main purposes of NEPA: informed public participation, government accountability and transparency. NEPA "ensures that the agency . . . will have available, and will carefully consider, detailed information concerning significant environmental impacts; it also guarantees that the relevant information will be made available to the larger [public] audience."[16] This use of CBI greatly compromises the public review process, because it makes the public reliant on the interpretation of the data by the submitter, which is not a disinterested or unbiased party. Clearly USDA also has evaluated the data in its EA, but this is not a substitute for the public review process, which is mandated by statute.

b. The EA improperly concludes that the impacts of planting hormone-containing safflower would be insignificant.

The essence of the scientific argument made by the USDA in the EA is that routes exist for pharma safflower to escape from the production sites (and potentially contaminate the food supply) and, upon close examination, the routes appear either unlikely or are blocked by containment measures imposed by USDA. The EA fails to analyze two stages of the safflower production process where contamination could occur, underestimates the likelihood of routes it did analyze, and overestimates the effectiveness of control measures.

i. The EA ignores two major routes of contamination.

Seed production and transport to the production site.

The EA fails to even mention the issues surrounding seed production, e.g., where the pharma safflower seed was produced,[17] the conditions under which it was produced, how and where the seed was stored before shipment, the distance and means of transport to the multiple production sites,

[13] EA, p 32, point 3
[14] SOPs detail the company's procedures for planting, harvesting, transporting, and storing pharma safflower to prevent accidental dispersal from the production sites.
[15] "Environmental Effects of Transgenic Plants: The Scope and Adequacy of Regulation," Committee on Environmental Impacts associated with Commercialization of Transgenic Plants, National Research Council, National Academy of Sciences, Washington, DC: National Academy Press. http://books.nap.edu/catalog/10258.html
[16] *Idaho Sporting Cong. v. Thomas*, 137 F.3d 1146, 1149 (9th Cir. 1998) (internal quotation marks omitted).
[17] The FR notice indicates that the seed was produced in Chile FR p. 5263

and storage at the production sites. This stage is an important opportunity for contamination as demonstrated by three recent instances of contaminated GE rice seed.[18]

Post-harvest transport

The EA fails to delineate and analyze the opportunities for contamination during post-harvest transport. The EA merely notes that after harvest, SemBioSys will ship bagged pharma safflower seeds to its Washington storage and processing facility following SOPs submitted to USDA.[19] Since the SOPs are CBI, it is impossible to know or to adequately comment if bagging, transport, and storage procedures will prevent escape of drug-containing seeds into or near food-crop fields.

An EA that essentially ignores two major routes of environmental contamination is facially inadequate, as it has not adequately discussed the potential environmental impacts, and in violation of NEPA. NEPA regulations require the analysis of both direct and indirect, as well as cumulative, effects in NEPA documents, including EAs.[20] CEQ's regulations mandate that federal agencies address all "reasonably foreseeable" environmental impacts of their proposed programs, projects, and regulations.[21]

ii. The EA underestimates routes of contamination and overestimates effectiveness of control measures.

USDA acknowledges that pharma genes and seeds could move off the field during crop production and establishes control measures to respond but they are inadequate. For example, the EA notes that dedicated equipment will be used for planting and harvesting but does not indicate if each of the up-to-ten production sites will have its own dedicated equipment.[22] If not, then the EA has not adequately addressed the possibility of pharma seed dispersal to food-crop fields from the movement of potentially incompletely cleaned equipment from site to site.

According to the EA, to rule out pharma pollen outcrossing to feed or food safflower, no safflower will be grown and no apiaries will exist within ten miles of the production sites.[23] However, the department does not explain how these ten-mile safflower-free and apiary-free zones will be monitored and enforced. Has SemBioSys entered into contracts or obtained commitments from all growers to refrain from growing safflower within a 10-mile radius of each production site? Will the company conduct farmer surveys during the planting season and inspect fields after crops have emerged to be certain the zone is free of safflower? SemBioSys asserts that no registered apiaries are found within the 10-mile radius of each site. How will the company be sure that no apiaries are established in the 2007 growing season?

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[18] "Statement by Dr. Ron DeHaven regarding APHIS hold on Clearfield CL131 long-grain rice," APHIS Statement, March 5, 2007; "USDA provides update for farmers on genetically engineered rice," APHIS Program Announcement, Biotechnology Regulatory Services, February 2007; Weiss, R. (2006). "Gene-altered profit-killer," *The Washington Post*, Sept. 21, 2006. http://www.washingtonpost.com/wp-dyn/content/article/2006/09/20/AR2006092001903.html.

[19] EA pp. 9, 23

[20] See 40 C.F.R. §§ 1508.8, .9, .13, .18.

[21] See 40 C.F.R. §§ 1508.8 & 1508.18.

[22] EA, p. 26

[23] Apiaries are important because bees cross pollinate safflower. P4-5

An agency cannot rely upon voluntary measures in making a determination that no significant environmental impact will result from its actions.

The EA also notes that wild bees and other pollinating insects are not expected to cross pollinate pharma and food safflower because the insects will be killed as farmers apply insecticides on adjacent wheat and barley fields to control insect pests. We hope that Washington State wheat and barley farmers are doing everything they can to preserve, not kill, wild bees and other pollinators. But in any case, reliance on presumed (not required) applications of insecticides to neighboring fields (not the GE safflower fields) to kill insect pollinators provides little or no assurance that they will not carry GE safflower pollen to conventional safflower. Again, an agency EA cannot rely upon voluntary measures in making a determination that no significant environmental impact will result from its actions.

In addition, even assuming such insecticide applications are made, there would be delicate timing issues to assure that pesticide applications on nearby fields would block cross pollination in safflower. How can USDA be sure that all fields will be sprayed and that all bees and other pollinators will be killed? Will SemBioSys survey farmers during the growing season to ensure that insecticides are applied at appropriate times to all fields? Will the company monitor for these insects during the growing season?

The EA has also not adequately addressed the potential for pharma safflower seeds to be dispersed to food-crop fields where they may grow as volunteers in the next growing season and then be harvested as a contaminant in a food crop such as wheat or barley. Extreme weather events could deposit seeds a considerable distance from production sites into wheat or barley fields. USDA ignores this possibility. In addition, there is no restriction on use of the GE safflower plots in the following season(s). GE safflower volunteers that sprout in any food-grade crop grown in subsequent seasons on the GE safflower plots would be difficult to detect and thoroughly eliminate. A precedent for this concern is the 2002 ProdiGene incident in which volunteer pharma corn was harvested along with food/feed soybeans grown on the same plot the following season, ultimately leading to the destruction of 500,000 bushels of contaminated soybeans. In addition, USDA has prohibited the cultivation of food-grade crops in subsequent seasons on plots on which pharma crops are grown.

Animals may carry seeds from production sites into adjacent food-crop fields. USDA addresses this possibility but ends up dismissing it with vague and unsubstantiated statements, which do not stand up to scrutiny. For example, the EA asserts without documentation that animals would find barley and wheat seeds more palatable than safflower seeds and would therefore be less likely to browse in the pharma safflower fields than in nearby cereal fields.[24] USDA acknowledges that birds could scavenge loose seeds after harvest but states that the birds prefer other safflower varieties and "would most likely be more attracted to the nearby cereal grain fields (emphasis added)."[25] None of these statements is substantiated and even if they were they do not rule out the possibilities for drug-containing safflower seeds to be dispersed by animals to food-crop fields where they may grow and contaminate next year's food crops.

[24] EA, p. 8
[25] EA, p8

Finally, USDA points to safflower's general lack of seed dormancy[26] to support its argument that pharma safflower will not germinate and grow as a volunteer in subsequent growing seasons.[27] However, a "general lack of seed dormancy" does not mean zero seed dormancy, leaving open the possibility that some pharma safflower seeds may germinate the following growing season in food-crop fields.

In summary, the EA fails to demonstrate that the production of pharma safflower would have no significant impact on the human environment and that no EIS is required. If an agency decides not to prepare an EIS, it must provide a "convincing statement of reasons" of why a project's impacts are insignificant.[28] USDA's EA fails to address potential impacts and provide necessary information for adequate public comment. The agency has not taken a "hard look" at the potential environmental impacts of its action.[29]

iii. The EA generally fails to address cumulative impacts, adequately address alternatives to the chosen action, or the controversial nature of this action.

In addition to the above deficiencies with the EA, USDA wholly failed to do cumulative impacts analyses where necessary, even though it is required to do so.[30] Further, USDA's analysis of alternatives in the EA was equally insufficient because USDA failed to adequately analyze the alternative it identified in the EA.[31] Finally, USDA failed to evaluate "the degree to which the effects on the quality of the human environment are likely to be highly controversial," as it is required to do.[32]

2. Potential Species Impacts

USDA has also failed to meaningfully assess the potential impacts of recombinant carp growth hormone produced in GE safflower on wild birds and animals that may consume the genetically engineered safflower seeds, including at least one threatened species, the Pygmy rabbit. The arguments USDA presents to support its conclusion that "…there will be no impact of carp growth hormone on birds or scavenging animals that could possibly ingest seed" are based on analogy, supposition and "lack of evidence" rather than scientific analysis.

First, USDA frankly admits that "the safety of carp growth hormone to humans and animals other than fish has never been investigated." Given the complete absence of scientific investigation, how does USDA make the unqualified assertion that recombinant carp growth hormone will have "no impact" on animals? USDA presents two arguments:

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[26] Meaning the seed typically would germinate before, not during, the next growing season

[27] EA, p. 11

[28] *Ocean Advocates v. U.S. Army Corps of Engineers*, 402 F.3d 846, 864 (9th Cir. 2005) (citing *Blue Mountains*, 161 F.3d at 1212).

[29] *Blue Mountains*, 161 F.3d at 1211.

[30] *See* 40 C.F.R. § 1508.25; *Kern v. U.S. Bureau of Land Mgmt*., 284 F.3d 1062, 1076 (9th Cir. 2002).

[31] *See Bob Marshall Alliance v. Hodel*, 852 F.2d 1223, 1228 (9th Cir. 1988).

[32] 40 C.F.R. § 1508.27(b)(4).

1) "(T)he long history of fish ingestion by numerous mammalian and avian species would indicate that it is not toxic at its natural biological levels."

2) "The ingestion safety of bovine somatotropin to mammals such as mice, cattle and humans has been described and it is deemed a safe protein even at high levels of exposure due to the breakdown of proteins in the mammalian and avian digestive process."

USDA's first argument is unacceptable on several counts. First, it fails to specify which mammalian or avian species have been demonstrated to suffer no adverse consequences from ingestion of carp growth hormone, or cite any study to support this assertion for any species. Second, there is no comparison of the levels of carp growth hormone in carp, versus the levels found in GE safflower seed, and no analysis of how much hormone-containing seed might be ingested by any species. Given this lack of analysis, any assertion about the non-toxicity of carp growth hormone to species that consume carp provides no insight into the potential effects of ingesting hormone-containing safflower seed. Finally, USDA glosses over the likely differences between natural carp growth hormone and the recombinant variety found in GE safflower seed. Recombinant proteins will nearly always differ, often in subtle ways but sometimes in basic structure as well, from their natural counterparts. SemBioSys's petition, which likely contains information of relevance to these questions, has been withheld from the public as confidential business information, preventing us from commenting more specifically on these matters.

The second argument rests on a presumed equivalence of bovine somatotropin to carp growth hormone, which the USDA itself admits does not obtain: "The growth hormones of cyprinids (carp-like fish) belong to a family possessing similar primary structure but are not closely related to those of other animals and share only 36% identity with human and about 40% with bovine somatotropins."

To the extent that this deeply flawed comparison offers any insight at all (which we doubt), there have in fact been studies demonstrating adverse effects on mammals that consume bovine somatropin. For instance, Health Canada's analysis of Monsanto's 90-day rat oral toxicity study, rBST (Nutrilac) 'Gaps Analysis' Report, describes the need for further toxicological studies of bovine somatotropin. In this study, rBST was absorbed into the bloodstream of the rats, and 20-30 percent of the rats given a medium to high dose of the hormone exhibited an immunological effect (meaning it affected them). The report notes that: "The full immunological and potentially toxicological consequences of this observation were not investigated."

It is completely unacceptable to draw any conclusions as to the safety of recombinant, GE safflower-produced, carp growth hormone to any animal species that might consume GE safflower seeds containing it from the "evidence" presented by USDA in its EA.

3. GIVEN USDA'S APPARENT INABILITY TO ESTABLISH AN OVERSIGHT SYSTEM THAT PROTECTS THE FOOD SUPPLY FROM CONTAMINATION BY PHARMA SAFFLOWER AND OTHER PHARMA FOOD CROPS, UCS RECOMMENDS THAT THE DEPARTMENT DENY THE SEMBIOSYS

APPLICATION AND IMMEDIATELY INSTITUTE A BAN ON THE OUTDOOR PRODUCTION OF ALL PHARMA FOOD CROPS.

USDA's 15-year history regulating pharma crops has demonstrated the immensity of the biological challenge inherent in forcing genes and seeds used in the open air to stay put.[33] Although USDA's regulations have gotten progressively stronger, even now as demonstrated in this EA, the USDA errs too often on the side of lax oversight.

But even if USDA were to strengthen its pharma crop oversight to a level that would theoretically completely protect the food supply, the new system would be enormously costly and complex to establish and implement. After considerable analysis, CFS endorses the view of Union of Concerned Scientists that that regulations sufficiently strong to protect the food supply would be well beyond the USDA's capacity to institute and oversee.[34]

Our judgment is backed by USDA's dismal record in implementing its current regulatory system, which is much simpler than one adequate to fully control the movement of pharma genes and seeds.

First, a December 2005 report from the USDA's Office of Inspector General (OIG) detailed significant deficiencies in the department's oversight of GE crop field tests, including trials of pharma crops. For example, the OIG found that the department failed to inspect pharma crop fields as often as promised and to ensure proper and timely disposal of the crops after harvest.[35]

Second, an analysis by Union of Concerned Scientists of USDA documents reveals serious deficiencies in the department's oversight system. In response to a Freedom of Information Act request for information on Ventria Bioscience's 2005 pharma rice production in North Carolina,[36] USDA released documents showing that it completed only three of five required inspections and failed to inspect the fields as promised during critical planting and harvesting events. The USDA also apparently allowed the company to ignore reporting requirements as the released documents contained only one of nine reports required from the company. Finally, the records showed no contact between USDA and Ventria after Hurricane Ophelia, which passed close to the site in September 2005, despite the fact that the severe weather might have spread pharma rice seeds into a nearby government-run rice-breeding plot.

Third, in the past year, three federal district court judgments have criticized the department for its poor oversight of GE crops.[37] In this string of recent cases, judges found that the environmental

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[33] CFS hereby incorporates by reference all comments on biopharm crops from its previous petition to USDA, *available at* http://www.centerforfoodsafety.org/pubs/PetitionBiopharmPlanting12.16.2002.pdf

[34] See Union of Concerned Scientists report, "Gone to Seed," at http://www.ucsusa.org/food_and_environment/genetic_engineering/gone-to-seed.html.

[35] USDA, Office of Inspector General, Southwest Region. 2005. Audit report: Animal and Plant Health Inspection Service controls over issuance of genetically engineered organism release permits. Audit 50601-8-Te, December. Online at *www.usda.gov/oig/webdocs/50601-08-TE.pdf*.

[36] For more information, including documents released by USDA, see the following UCS web page: UCS uncovers lax USDA oversight of pharma crops. Online at *www.ucsusa.org/food_and_environment/genetic_engineering/usda-ventria-oversight.html*.

[37] *See* CFS press releases, *available at* http://www.centerforfoodsafety.org/Alfalfa_DecisionPR2_14_07.cfm , http://www.centerforfoodsafety.org/GTBC_DecisionPR_2_7_07.cfm , & http://www.centerforfoodsafety.org/Hawaii%20biopharm%20crop%20judgement%20Aug%2010,%202006.cfm

assessments done by the USDA prior to the testing or commercialization of several genetically engineered (GE) crops was either non-existent or severely lacking, and in violation of our nation's environmental protection laws.[38]

Finally, in the last six months, three different GE traits have been found in non-GE rice varieties in the U.S. rice supply, causing substantial hardship to rice farmers and the rice industry as a whole.[39]

Conclusion

In light of the potential economic, environmental, and public health consequences of contamination with pharma and industrial genes and the USDA's inability to prevent such contamination, the most prudent policy is for USDA to ban the outdoor production of pharma food crops. CFS urges USDA to adopt and implement such a policy. Short of that, CFS finds that the significant unanswered or inadequately answered safety questions that our analysis has discovered warrant a full environmental impact statement (EIS) under the National Environmental Protection Act (NEPA).

Respectfully submitted,

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[38] *Id.*
[39] See footnote 13 for references.