



THE CENTER FOR FOOD SAFETY

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Comments to EPA on (1) Notice of Receipt of Application to Register New Use of Dicamba on Dicamba Glufosinate Tolerant MON 88701 Cotton; (2) Notice of Receipt of Pesticide Petition to Request to Establish Tolerances for Residue of Dicamba in Cottonseed and Cotton Gin Byproducts

On December 19, 2012, EPA announced in the Federal Register that the agency has received an application from Monsanto Company (Monsanto) to register the proposed new use of the herbicide dicamba (diglycolamine salt of dicamba) on Monsanto's dicamba- and glufosinate- resistant MON 88701 Cotton (MON 88701 cotton)¹ under Section 3(c) of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) (hereafter Dicamba New Use Registration Application).² In a separate Federal Register notice published on the same day, EPA announced that Monsanto has also filed a petition to modify existing tolerances for residue of dicamba and its metabolites in cottonseed and cotton gin byproducts,³ pursuant to Section 408 of the Federal Food, Drug, and Cosmetic Act (FFDCA)⁴ (hereafter Dicamba Tolerance Petition).⁵ The Center for Food Safety (CFS) hereby submits the following comments concerning issues that EPA should consider in its review of Monsanto's Dicamba New Use Registration Application and Dicamba Tolerance Petition under FIFRA, the FFDCA, and the Endangered

¹ 77 Fed. Reg. 75,153, 75,154 (Dec. 19, 2012).

² 7 U.S.C. §§ 136 *et seq.*

³ 77 Fed. Reg. 75,083, 75,084 (Dec. 19, 2012).

⁴ 21 U.S.C. § 346a.

⁵ 21 U.S.C. § 346a.

Species Act (ESA)⁶.

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.⁷ CFS represents more than 200,000 members throughout the country that support sustainable forms of food production such as organic agriculture and regularly purchase organic products. Concurrently, CFS is also submitting a separate set of comments and supporting documents cited therein prepared by Mr. Bill Freese and Dr. Martha Crouch, Ph.D (CFS Science Comments) that discusses in detail the issues that EPA must consider in reviewing Monsanto's two submissions.

SUMMARY

(1) Monsanto's Dicamba New Use Registration

Monsanto's proposed new use, if registered, would permit the use of the dicamba herbicide (diglycolamine salt of dicamba) on MON 88701 cotton, which has been genetically engineered (GE) to withstand direct applications of high rates of the herbicides dicamba, glufosinate and glyphosate.⁸ Dicamba is little used in U.S. agriculture; more specifically, it is rarely used in U.S. cotton production. This is because dicamba is a broad-leaf herbicide with high potential to drift and volatilize, resulting in crop injury. The proposed registration of dicamba on MON 88701 cotton would facilitate a sharp increase in agricultural use of dicamba, as well as an overall increase in herbicide use in U.S. agriculture since MON 88701 cotton is resistant to three herbicidal modes of action. Moreover, the resulting increase in dicamba use poses serious threats to U.S. agriculture via drift injury and development of herbicide-resistant weeds. EPA must carefully consider these unreasonable adverse effects in the agency's review of Monsanto's Dicamba New Use Registration.

In preparing its risk assessment of Monsanto's Dicamba New Use Registration Application, EPA must assess whether the proposed new use of dicamba on MON 88701 cotton as part of a dicamba-resistant crop system causes changes to existing use patterns of dicamba. EPA must also include in its assessment any direct and indirect impacts of the proposed new use of dicamba on MON 88701 cotton as part of a dicamba-resistant crop system. Finally, EPA must consider additional restrictions or mitigation measures that may be placed on the proposed new use to reduce any unreasonable adverse effects on U.S. agriculture and the overall environment. Under FIFRA, EPA cannot register the proposed new use of dicamba if the agency determines that these changes in use patterns and their related impacts will result in unreasonable adverse effects on the environment.

⁶ 16 U.S.C. §§ 1531-1544.

⁷ See generally www.centerforfoodsafety.org.

⁸ Monsanto, *2013 Research & Development Pipeline: Cotton*, <http://www.monsanto.com/products/Pages/cotton-pipeline.aspx> (last visited Jan. 15, 2013).

EPA should only consider Monsanto's Dicamba New Use Registration Application under FIFRA's unconditional registration criteria.⁹ Monsanto's Dicamba New Use Registration Application proposes the unprecedented use of dicamba on the company's herbicide-resistant GE cotton variety specifically designed to withstand the application of dicamba, in addition to glyphosate and glufosinate, thus establishing a new generation of herbicide-resistant crop system in U.S. agriculture. EPA's risk assessment and registration determination of this proposed new use must involve a critical review of all relevant data; as such, EPA should not conditionally register the proposed new use of dicamba on MON 88701 cotton under FIFRA Section 3(7).¹⁰ Moreover, EPA must prepare an Environmental Impact Statement (EIS) and take a "hard look" at all reasonably foreseeable consequences of registering dicamba use on dicamba-resistant MON 88701 cotton.

Finally, given the unprecedented nature and significant impacts of Monsanto's new use proposal, EPA must ensure meaningful public input by (1) publishing all relevant information as well as the agency's draft risk assessment; and (2) providing a second opportunity for public comment.

(2) Monsanto's Dicamba Tolerance Petition

Monsanto's Dicamba Tolerance Petition proposes modifying the current tolerance level of dicamba residue in or on undelinted cotton seed, from the current 0.2 ppm to 3 ppm.¹¹ The Dicamba Tolerance Petition also proposes the establishment of new tolerance for dicamba residue in or on cotton gin byproducts, at 70 ppm.¹²

As explained in detail in separately-submitted CFS Science Comments, increase exposure to dicamba carries significant human health harms.¹³ Under the FFDCFA, EPA has a duty to set tolerance levels that ensure the residue of dicamba under the proposed new use is "safe," meaning that EPA must determine that "there is a reasonable certainty no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information."¹⁴ Thus, EPA's determination of safety requires that EPA takes into account the aggregate human exposure to dicamba residue, not just from dietary pathways but also exposure via agricultural uses, residential uses, and groundwater or surface water. As pointed out in separately-submitted CFS Science Comments, contamination of ground and surface waters by dicamba frequently occurs, and must be considered by the EPA in evaluating Monsanto's Dicamba Tolerance Petition. Moreover, EPA should also take into account the proposed new use pattern of dicamba on MON 88701 cotton, which will result in more frequent applications of dicamba, not to mention the prolonged use of

⁹ See 7 U.S.C. §136a(c)(5).

¹⁰ See 7 U.S.C. §136a(c)(7).

¹¹ See 77 Fed. Reg. 75,083, 75.084 (Dec. 19, 2012); 40 C.F.R. § 180.227 (Dicamba residue tolerances).

¹² See 77 Fed. Reg. 75,083, 75.084 (Dec. 19, 2012); 40 C.F.R. § 180.227 (Dicamba residue tolerances).

¹³ See CFS Science Comments (submitted separately).

¹⁴ 21 U.S.C. § 346a(b)(2)(A).

dicamba as part of a dicamba-resistant crop system. Given the clear potential for serious health implications from exposure to dicamba, the vastly increased use that would be facilitated by the proposed registration and new tolerances, the proposed new tolerance levels of dicamba in or on cottonseed and cotton gin byproducts are clearly contrary to the interests of farmers and the general public.

RELEVANT LEGAL STANDARDS

Federal Insecticide, Fungicide, and Rodenticide Act

FIFRA authorizes EPA to regulate the registration, use, sale, and distribution of pesticides in the United States. FIFRA defines pesticides broadly to include herbicides—“any substance or mixture of substances intended for use as a plant regulator, defoliant, or desiccants.”¹⁵

Pursuant to FIFRA, EPA oversees both initial registration of an active ingredient as well as any new uses of the registered active ingredient. EPA’s FIFRA-implementing regulations define “new use”:

New use, when used with respect to a product containing a particular active ingredient, means: (1) Any proposed use pattern that would require the establishment of, the increase in, or the exemption from the requirement of, a tolerance or food additive regulation under section 408 or 409 of the Federal Food, Drug and Cosmetic Act; (2) Any aquatic, terrestrial, outdoor, or forestry use pattern, if no product containing the active ingredient is currently registered for that use pattern; or (3) Any additional use pattern that would result in a significant increase in the level of exposure, or a change in the route of exposure, to the active ingredient of man or other organisms.¹⁶

Section 3(c) of FIFRA states that a manufacturer must submit an application to register any new uses of a registered active ingredient.¹⁷ EPA’s evaluation of the proposed pesticide use must take into account its “impacts on human health, occupational risks, and environmental risks.”¹⁸ EPA cannot register the pesticide unless EPA concludes that the proposed new use “will not generally cause unreasonable adverse effects on the environment” when “perform[ing] its intended function” and “when used in accordance with widespread and commonly recognized practice.”¹⁹ “Unreasonable adverse effects on the environment” includes “any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide.”²⁰

¹⁵ 7 U.S.C. § 136(u)(2).

¹⁶ 40 C.F.R. § 152.3(p).

¹⁷ 7 U.S.C. § 136a(c)(1); 40 C.F.R. § 152.42.

¹⁸ EPA, *Overview of Risk Assessment in the Pesticide Program* (May 9, 2012), at http://www.epa.gov/pesticides/about/overview_risk_assess.htm.

¹⁹ 7 U.S.C. § 136a(c)(5).

²⁰ 7 U.S.C. §136(bb).

Federal Food, Drug, and Cosmetic Act

The FFDCA²¹ prohibits the introduction of “adulterated” food into interstate commerce.²² The Act requires that where use of a pesticide will result in any pesticide residue being left on food, EPA must either set a “tolerance” level for the amount of allowable pesticide residue that can be left on the food, or set an exemption of the tolerance requirement.²³

The FFDCA mandates EPA to “establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the EPA Administrator determines that the tolerance is safe.”²⁴ For a tolerance level to be “safe,” the statute requires EPA determine “that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”²⁵ “Aggregate exposure” includes not only dietary exposure through food consumption, but also includes “exposures through water and residential uses.”²⁶

Endangered Species Act

As recognized by the Supreme Court, the ESA is “the most comprehensive legislation for the preservation of endangered species ever enacted by any nation.”²⁷ The ESA’s statutory scheme “reveals a conscious decision by Congress to give endangered species priority over the ‘primary missions’ of federal agencies.”²⁸ Federal agencies are obliged “to afford first priority to the declared national policy of saving endangered species.”²⁹ “Because EPA has continuing authority over pesticide regulation, it has a continuing obligation to follow the requirements of the ESA.”³⁰

Section 7(a)(2) of the ESA requires every federal agency to consult the appropriate federal fish and wildlife agency—Fish and Wildlife Service (FWS) in the case of land and freshwater species and the National Marine Fisheries Service (NMFS) in the case of marine species—to “insure” that the agency’s actions are not likely “to jeopardize the continued existence” of any listed species or “result in the destruction or adverse modification” of critical habitat.³¹ The ESA’s implementing regulations broadly define agency action to include “all activities or programs of any kind authorized, funded or carried out ... by federal agencies,”

²¹ 21 U.S.C. § 301 *et seq.*

²² 21 U.S.C. § 331.

²³ 21 U.S.C. § 346a(1).

²⁴ 21 U.S.C. § 342(a)(2)(A) (emphasis added); *see also* 40 C.F.R. § 180.1(f).

²⁵ 21 U.S.C. § 346(a)(2)(A)(ii).

²⁶ *Natural Res. Def. Council v. Whitman*, No. C 99-03701-WHA, 2001 WL 1221774 (N.D. Cal. Nov. 7, 2001).

²⁷ *Tenn. Valley Authority v. Hill*, 437 U.S. 153, 180 (1978).

²⁸ *Id.* at 185.

²⁹ *Id.*

³⁰ *Wash. Toxics Coal. v. EPA*, 413 F.3d 1024, 1033 (9th Cir. 2005).

³¹ 16 U.S.C. § 1536(a)(2); *see also* 50 C.F.R. § 402.01(b).

including the granting of permits and “actions directly or indirectly causing modifications to the land, water or air.”³² A species’ “critical habitat” includes those areas identified as “essential to the conservation of the species” and “which may require special management considerations or protection.”³³

To facilitate compliance with section 7(a)(2)’s prohibitions on jeopardy and adverse modification, the ESA requires each federal agency that plans to undertake an action to request information from the expert agency “whether any species which is listed or proposed to be listed [as an endangered species or a threatened species] may be present in the area of such proposed action.”³⁴ If FWS/NMFS advises the agency that listed species or species proposed to be listed may be present, the agency must then prepare a biological assessment for the purpose of identifying any such species that are likely to be affected by the proposed agency action.³⁵

If, based on a biological assessment, an agency determines that its proposed action may affect any listed species and/or their critical habitat, the agency generally must engage in formal consultation with FWS/NMFS.³⁶ At the end of the formal consultation, FWS/NMFS must provide the agency with a “biological opinion” detailing how the proposed action will affect the threatened and endangered species and/or critical habitats.³⁷ If FWS/NMFS concludes that the proposed action will jeopardize the continued existence of a listed species or result in the destruction or adverse modification of critical habitat, the biological opinion must outline “reasonable and prudent alternatives” to the proposed action that would avoid violating ESA section 7(a)(2).³⁸

Pending the completion of formal consultation with the expert agency, an agency is prohibited from making any “irreversible or irretrievable commitment of resources with respect to the agency action which has the effect of foreclosing the formulation or implementation of any reasonable and prudent alternative measures.”³⁹

National Environmental Policy Act

NEPA requires federal agencies to prepare a detailed environmental impact statement (EIS) for all “major Federal actions significantly affecting the quality of the human environment.”⁴⁰ 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.”⁴¹

³² 50 C.F.R. § 402.02.

³³ 16 U.S.C. § 1532(5)(A).

³⁴ 16 U.S.C. § 1536(c)(1); *see also* 50 C.F.R. § 402.12(c).

³⁵ 16 U.S.C. § 1536(c)(1); *see also* 50 C.F.R. § 402.12(c).

³⁶ 50 C.F.R. § 402.14.

³⁷ 16 U.S.C. § 1536(b); 50 C.F.R. § 402.14.

³⁸ 16 U.S.C. § 1536(b)(3)(A).

³⁹ 16 U.S.C. § 1536(d).

⁴⁰ 42 U.S.C. § 4332(2)(C).

⁴¹ *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349(1989).

Whether there may be a significant effect on the environment requires consideration of two broad factors: context and intensity. A number of factors should be considered in evaluating intensity, including, “[t]he degree to which the proposed action affects public health or safety,” “[t]he degree to which the effects on the quality of the human environment are likely to be highly controversial,” “[t]he degree to which the possible effects on the human environment are highly uncertain or involve unique or unknown risks,” “[t]he degree to which the action may establish a precedent for future actions with significant effects or represents a decision in principle about a future consideration,” “[w]hether the action is related to other actions with individually insignificant but cumulatively significant impacts,” and “[t]he degree to which the action may adversely affect an endangered or threatened species or its habitat.”⁴²

NEPA also established the Council on Environmental Quality (CEQ) and charged CEQ with the duty of overseeing the implementation of NEPA.⁴³ The regulations subsequently promulgated by CEQ, 40 C.F.R. §§ 1500-08, implement the directives and purpose of NEPA, and “[t]he provisions of [NEPA] and [CEQ] regulations must be read together as a whole in order to comply with the spirit and letter of the law.”⁴⁴ CEQ’s regulations are applicable to and binding on all federal agencies.⁴⁵ Among other requirements, CEQ’s regulations mandate that federal agencies address all “reasonably foreseeable” environmental impacts of their proposed programs, projects, and regulations.⁴⁶

COMMENTS

The proposed new use of dicamba on Monsanto’s dicamba-resistant MON 88701 cotton, which has been specifically engineered to resist the application of dicamba, marks a significant departure from existing use patterns of dicamba on conventional cotton. Monsanto’s Dicamba New Use Registration Application relates to the herbicidal component of Monsanto’s dicamba-resistant crop system of dicamba-resistant cotton. Monsanto’s dicamba-resistant crop system would facilitate weed control based primarily on post-emergence applications of dicamba and/or glufosinate on MON 88701 cotton.⁴⁷ The proposed dicamba-resistant crop system is explicitly intended for farmers whose fields are infested with weeds resistant to glyphosate, which have spread across approximately 17 million acres of U.S. cropland, largely due to unregulated use of glyphosate in the context of the Roundup Ready (glyphosate-resistant) crop systems, though they may also be used by farmers with weeds resistant to other modes of action, such as ALS inhibitors and triazines.⁴⁸

⁴² 40 C.F.R. § 1508.27(b)(2), (4), (5), (6), (7), (9).

⁴³ See 42 U.S.C. §§ 4321, 4344.

⁴⁴ 40 C.F.R. § 1500.3.

⁴⁵ 40 C.F.R. §§ 1500.3, 1507.1; see, e.g., *Hodges v. Abraham*, 300 F.3d 432, 438 (4th Cir. 2002).

⁴⁶ See 40 C.F.R. §§ 1502.4, 1508.8, 1508.18, & 1508.25.

⁴⁷ Monsanto, *2013 Research & Development Pipeline: Cotton*,

<http://www.monsanto.com/products/Pages/cotton-pipeline.aspx> (last visited Jan. 15, 2013).

⁴⁸ *Id.*

Similarly, the proposed increase in tolerance level of dicamba residue in or on cottonseed, from 0.2 ppm to 3 ppm, and the new tolerance level of dicamba residue in or on cotton gin byproducts at 70 ppm, must be analyzed in the context of the significant increase in the use of dicamba on cotton that will accompany the proposed registration of dicamba use on Monsanto's dicamba-resistant MON 88701 cotton. The novelty of the proposed new use demands that EPA carefully consider the "economic, social, and environmental costs" associated with the proposed new use and proposed tolerances in its risk assessment.⁴⁹

I. EPA Should Not Conditionally Register Monsanto's Dicamba New Use Registration Application

The novelty of the proposed new use of dicamba and the changes in existing dicamba use patterns as applied in the dicamba-resistant crop system warrants EPA to commence a complete review of Monsanto's Dicamba New Use Registration Application for unconditional registration only. EPA's FIFRA implementing regulations provide that EPA may initiate review using the unconditional registration criteria in FIFRA Section 3(c)(5)—as opposed to conditional registration criteria set forth in FIFRA Section 3(c)(7)—"in special cases where [EPA] finds immediate review to be warranted."⁵⁰

Under FIFRA's criteria for unconditional registration, EPA can register the proposed new use of dicamba on dicamba-resistant MON 88701 cotton only if EPA concludes that the proposed new use will not have "unreasonable adverse effects on the environment" after reviewing all data in EPA's possession.⁵¹ Unlike a conditional registration pursuant to FIFRA Section 3(c)(7), unconditional registration requires that EPA determine that "no additional data is necessary" for the agency to assess "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the use of any pesticide."⁵² In contrast, EPA can conditionally register a new use application so long as the agency concludes that the proposed new use will "not significantly increase the risk of any unreasonable adverse effect on the environment" and that the "proposed use [is] identical or substantially similar to any currently registered pesticide and use thereof."⁵³

As explained in the comments herein and separately-submitted CFS Science Comments, existing scientific studies and academic papers demonstrate that the proposed new use patterns of dicamba on GE, dicamba-resistant MON 88701 cotton may have significant adverse impacts on human health and the environment. The proposed registration of dicamba for use on MON 88701 cotton raises a number of serious issues that EPA has never confronted in any past registration decisions of new uses of dicamba. These issues arise from an inescapable biological fact: MON 88701 cotton will facilitate greatly altered usage patterns of phenoxy auxin herbicides like dicamba vis-à-vis past usage on conventional cotton. Thus, the proposed new use would

⁴⁹ 7 U.S.C. §136(bb).

⁵⁰ 40 C.F.R. § 152.111 (giving EPA discretion to decide whether to use conditional registration or unconditional registration criteria).

⁵¹ 7 U.S.C. 136a(c)(5).

⁵² 7 U.S.C. §136(bb).

⁵³ 7 U.S.C. § 136a(c)(7).

substantially alter the existing use of dicamba as applied to Monsanto's dicamba-resistant MON 88701 cotton. Thus, EPA must assess Monsanto's Dicamba New Use Registration Application for the proposed use of dicamba on Monsanto's dicamba-resistant MON 88701 cotton strictly under FIFRA criteria for unconditional registration.

II. NEPA Demands that EPA Take a Hard Look at All Reasonable Foreseeable Environmental Impacts Stemming from Monsanto's Proposed Use of Dicamba on Dicamba-Resistant MON 88701 Cotton

Moreover, EPA must reject conditional registration of the proposed new use of dicamba on Monsanto's dicamba-resistant MON 88701 cotton because EPA's risk assessment of the proposed new use must also satisfy the agency's duties under NEPA. While it is true that some federal courts have excused EPA from "formal compliance with NEPA," that is only where its FIFRA analysis is the functional equivalent of an EIS, and FIFRA's conditional registration criteria falls short of the "hard look" that NEPA mandates on all federal agencies, including EPA.⁵⁴

As explained above, EPA should not conditionally register Monsanto's new uses. But even if it does, it must comply with NEPA and prepare an EIS. A conditional registration violates NEPA by allowing EPA to register a pesticide or its use without consideration of "detailed information concerning significant environmental impacts," and excludes public scrutiny and participation on potential significant environmental effects stemming from the registered use.⁵⁵ For its FIFRA analysis to functionally satisfy NEPA's hard look requirement, EPA must demand that Monsanto submit a complete application, satisfy any data gaps, and conduct and produce peer-reviewed studies on any potential unreasonable adverse effects on the environment stemming from Monsanto's proposed new use of dicamba on Monsanto's dicamba-MON 88701 cotton.

III. The Proposed New Use of Dicamba on Monsanto's Dicamba-Resistant MON 88701 Cotton Would Significantly Alter Use Patterns and Increase Overall Use of Dicamba

Under FIFRA, EPA cannot register a pesticide for a specified use if such use will result in "unreasonable adverse effects on the environment."⁵⁶ EPA must determine whether Monsanto's proposed use of dicamba as part of a dicamba-resistant crop system will lead to "any unreasonable risk to man or the environment, taking into account the economic, social, and environmental costs and benefits of the [new] use of [dicamba]" on Monsanto's dicamba-resistant cotton. As explained in more detail in separately-submitted CFS Comments, the proposed new use of existing dicamba salt formulation on GE, MON 88701 cotton will have significant "economic, social and environmental costs" such that its use will "cause unreasonable adverse effects on the environment."⁵⁷ EPA should consider these costs in its risk assessment of

⁵⁴ Cf. *Merrell v. Thomas*, 807 F.2d 776 (9th Cir. Or. 1986).

⁵⁵ See *Robertson v. Methow Valley Citizens Council*, 490 U.S. 332, 349 (1989).

⁵⁶ *Id.*

⁵⁷ See 7 U.S.C. § 136a(c)(5).

Monsanto's Dicamba New Use Registration Application.

Under FIFRA, EPA has the authority to request additional information from the applicant.⁵⁸ The studies and data cited herein highlight potential risks and effects on U.S. agriculture, plants and species, mankind and the environment that EPA must evaluate critically in its risk assessment. At a minimum, EPA must request Monsanto to submit additional data and documents where appropriate to ensure that the proposed new use of dicamba as part of Monsanto's dicamba-resistant crop system would not have "unreasonable adverse effects on the environment."

EPA should critically analyze how the proposed new use registration will increase and alter existing uses of dicamba when applied to dicamba-resistant MON 88701 cotton. EPA must analyze the increase in both volume and frequency of dicamba use in U.S. agriculture, as well as any impacts stemming from such an increase in volume and frequency. In doing so, EPA should look beyond the existing total maximum annual application of dicamba allowed to the amount of dicamba that is currently being applied on conventional cotton. EPA should require Monsanto to submit data and models to predict the amount of increase in dicamba use that is likely to occur, the geographic regions where the new dicamba formulation might be used, as well as any environmental effects associated with such a massive increase in dicamba use.

EPA should consider the adverse environmental effects stemming from the increased dicamba use should EPA register dicamba for the proposed new use on the dicamba-resistant cotton. The use of accompanying herbicides in other herbicide-resistant crop systems has dramatically increased overall pesticide and herbicide use in the past thirteen years.⁵⁹ The registered new use of dicamba on dicamba-resistant MON 88701 cotton would lead to a massive increase in the amount of dicamba being applied in U.S. agriculture. This increase in dicamba use is certain because currently, dicamba is rarely applied to conventional cotton.⁶⁰ As explained in detail in separately-submitted CFS Science Comments, MON 88701 cotton's engineered resistance to dicamba is estimated to significantly increase dicamba use on U.S. cotton fields. Moreover, because Monsanto's dicamba-resistant MON 88701 cotton is also stacked with resistance to glyphosate and glufosinate, EPA's approval of the proposed new use of dicamba on MON 88701 cotton would contribute to an overall increase of herbicides used on U.S. cotton acreage.⁶¹

Dicamba Applications and Herbicide-Resistant Weeds

Monsanto's dicamba-resistant MON 88701 cotton is targeted for use especially by farmers with glyphosate-resistant weeds, but also those with weeds resistant to other classes of

⁵⁸ 7 U.S.C. § 136a(c)(3)(A).

⁵⁹ Charles Benbrook, Organic Ctr., *Impacts of Genetically Engineered Crops on Pesticide Use: The First Thirteen Years* (Nov. 2009).

⁶⁰ See separately-submitted CFS Science Comments and references cited therein.

⁶¹ *Id.*

herbicide, such as ALS inhibitors and triazines.⁶² Several of the most problematic herbicide-resistant weed species (e.g. common Waterhemp and Palmer amaranth) emerge not just in one “flush,” but rather through much of the season, leading to multiple applications. In addition, the likely evolution of “creeping resistance” to dicamba (e.g. in common Waterhemp) with use of dicamba-resistant crop systems would put upward pressure on usage rates over time. The likely impacts of the proposed registrations on weed resistance are elaborated further below and discussed in detail in separately-submitted CFS Science Comments.

IV. EPA Should Consider All Economic, Social and Environmental Costs Stemming from Monsanto’s Proposed New Use of Dicamba on Novel Dicamba-Resistant MON 88701 Cotton and Monsanto’s Proposed Tolerances for Dicamba Residue in or on Cotton and Cotton Gin Byproducts

Injury from Dicamba Drift

In its risk assessment of Monsanto’s Dicamba New Use Registration Application, EPA must consider the economic and environmental costs stemming from the injury to other commercial crops, as well as non-target organisms, from the drift of the proposed new use of dicamba on MON 88701 cotton.

Dicamba is a volatile herbicide that is prone to drift beyond the field of application to damage neighboring crops and wild plants.⁶³ Dicamba vapor injures most broadleaf (i.e. non-grass) plants at extremely low levels.⁶⁴ Particularly sensitive crops include grapes, sunflower, peanut, potato, soybean, cotton and tomato.⁶⁵

Indeed, crop injury is a significant biological restraint on the use of dicamba with currently grown conventional cotton. In contrast, MON 88701 cotton is engineered to withstand high rates of dicamba. Because broadleaf crops are extremely sensitive to dicamba, crop injury bars any post-emergence use of dicamba on cotton. MON 88701 cotton thus dramatically loosens the biological constraint of crop injury that currently limits when dicamba can be safely applied to currently grown cotton varieties. Thus, the use of dicamba under the proposed registration on MON 88701 cotton would greatly increase drift injury to crops over already high levels by enabling use, on much greater acreage, applied later in the season when neighboring crops and plants have leafed out or are at reproductive stages and are thus more susceptible to drift injury.⁶⁶

⁶² Monsanto, *2013 Research & Development Pipeline: Cotton*,

<http://www.monsanto.com/products/Pages/cotton-pipeline.aspx> (last visited Jan. 15, 2013).

⁶³ EPA, Reregistration Eligibility Decision for Dicamba and Associated Salts 14 (June 8, 2006), available at http://www.epa.gov/oppsrrd1/REDs/dicamba_red.pdf.

⁶⁴ *Id.*

⁶⁵ Lee, H.E., C.A. Burdick and D. M. Olszyk, 2005. GIS-based risk assessment of pesticide drift case study: Fresno County, California. US EPA/600/R-05/029, March 2005.

<http://www.epa.gov/wed/pages/publications/authored/EPA600R-05029PesticideDriftLee.pdf>

⁶⁶ Kruger GR, Johnson WG, Doohan DJ, Weller SC (2012) Dose Response of Glyphosate and Dicamba on Tomato (*Lycopersicon esculentum*) Injury. *Weed Technology* 26: 256–260.

EPA must critically assess the potential drift injury that would result from the proposed use of dicamba on dicamba-resistant MON 88701 cotton. Although Monsanto claims that it will only register the use for a dicamba salt (diglycolamine salt of dicamba) that is less volatile than other registered dicamba salts, spray drift (versus vapor drift) has more to do with weather conditions, application equipment, and the applicators' practices than with the properties of the herbicide formulation. Even if the chosen dicamba salt is less drift-prone, any improvement in mitigating drift that it might present will be swamped by vastly increased use. In any case, neither EPA nor Monsanto will be able to prevent the use of cheaper, highly-drift prone formulations of the same dicamba salt. EPA must critically assess the volatility of the registered dicamba salt, as well as consider any mitigation measures that will reduce potential drift injury to other agricultural crops and wild plant species.

Drift from dicamba applications under Monsanto's proposed new use could also be injurious to wild plants; an environmental cost that EPA should include in its risk assessment. EPA is well aware that dicamba is a particularly potent poison for many species of plants, especially dicotyledons (broadleaf plants) that are sensitive to very low levels. Hormone-mimic herbicides such as dicamba injure some plants at lower concentrations than other widely used herbicides. If dicamba is moving off-site far enough to cause injury to crops, it is undoubtedly also causing injury to wild plants. Drift of dicamba is most likely to impact vegetation near the site where it is applied, so borders of fields and adjacent fencerows, wetlands, woodlands, riparian areas, and old-fields are vulnerable. These areas provide most of the biodiversity found in agricultural landscapes.⁶⁷

EPA must consider this significant adverse impact of injury to non-target organisms in its risk assessment of Monsanto's new use registration application. In doing so, EPA must make a realistic prediction of the amount of dicamba that will be used on MON 88701 cotton compared to conventional varieties in order to evaluate the impacts of Monsanto's Dicamba New Use Registration Application. For more detailed discussion, please see separately-submitted CFS Science Comments.

Weed Resistance

EPA should also consider how the registered new use of dicamba on dicamba-resistant cotton will promote the development of resistant weed, which in turn results in applications of more toxic herbicides to the detriment of human health, animal species, and the environment, as well as an increase in the costs of weed control for farmers.⁶⁸ In 2007, U.S. farmers spent \$4.2 billion dollars to apply 442 million lbs. of herbicide, and uncounted billions more on technology fees for herbicide-resistance traits in major crops. As farmers gradually came to rely more and more on herbicides as the preferred and then often the sole means to control weeds, herbicide-

⁶⁷ Boutin, C. and B. Jobin (1998). Intensity of agricultural practices and effects on adjacent habitats. *Ecological Applications* 8(2): 544 – 557

⁶⁸ See *Love v. Thomas*, 858 F.2d 1347 (9th Cir. 1988) (overturning EPA's decision to suspend a pesticide's registration where EPA failed to consider economic costs to farmers due to inability to continue use of the registered product).

resistant weeds have become increasingly severe and costly. Farmers respond by applying evermore herbicides. Increasing the rate and number of applications, however, often rapidly leads to further resistance, followed by adding additional herbicides into the mix, beginning the resistance cycle all over again, just as overused antibiotics breed resistant bacteria. This process, dubbed the pesticide treadmill, has afflicted most major families of herbicides.

Herbicide-resistant weeds are both the consequence of unsustainable weed control practices, and a major factor making weed management still less sustainable. Adverse impacts of herbicide-resistant weeds include the increased costs incurred by growers for additional herbicides to control them, greater farmer exposure to herbicides and consumer exposure to herbicide residues in food and water, soil erosion and greater fuel use and emissions from increased use of mechanical tillage to control resistant weeds, environmental impacts from herbicide runoff, and in some cases substantial labor costs for manual weed control.

EPA should consider how the proposed new use of dicamba as part of Monsanto's dicamba-resistant crop system will promote the growth of herbicide-resistant weeds, a significant economic cost to agricultural production. Monsanto's dicamba-resistant MON 88701 cotton will foster an overreliance on dicamba, which the crop is engineered to resist. Indeed, common Waterhemp, regarded as one of the worst weeds in the Corn Belt, which already has developed resistance to more than six modes of action, was recently discovered to have developed resistance to dicamba.⁶⁹ The weed scientists who discovered this resistant weed population clearly understand the likelihood that dicamba-resistant crop systems—"if used as the primary tool to manage weeds already resistant to other herbicides," the hallmark of these systems—will lead to still more intractable, multiple herbicide-resistant weeds:

New technologies that confer resistance to 2,4-D and dicamba (both synthetic auxins) are being developed to provide additional herbicide options for postemergence weed control in soybean and cotton. The development of dicamba resistant waterhemp in this field is a reminder and a caution that these new technologies, if used as the primary tool to manage weeds already resistant to other herbicides such as glyphosate, atrazine or ALS-inhibitors, will eventually result in new herbicide resistant populations evolving.⁷⁰

Thus, in its risk assessment, EPA must consider the likelihood of weed resistance and their associated environmental, economic and human health impacts. For more detailed analysis on the issue of weed resistance, please see separately-submitted CFS Science Comments.

Harm to Non-Target Crops and Plants from Dicamba

Organisms in field edges could receive higher and more frequent doses of dicamba during the growing season when it is used with MON 88701 cotton, as well as an increase of dicamba residue that would be allowed on the cotton crop under Monsanto's Dicamba Tolerance Petition.

⁶⁹ UNL (2011). "2,4-D resistant waterhemp found in Nebraska," University of Nebraska-Lincoln CropWatch, October 20, 2011.

⁷⁰ *Id.*

As explained above and in separately submitted CFS Science Comments, the increase in the use and residue levels of dicamba on cotton are more likely to coincide with life-stages of plants that are the most sensitive to injury because MON 88701 cotton itself is less sensitive to injury after planting. Since the use of dicamba on MON 88701 cotton after planting is a completely new practice, the difference in timing is even more pronounced and likely to cause harm.

Another way that the proposed new use of dicamba on MON 88701 cotton cropping systems and new tolerance level on cottonseed will increase exposure to dicamba is by an increase in the total number of cotton acres that are treated with dicamba, which is hardly used on cotton currently. At a landscape level this increase will result in a larger number of individuals of a wider array of species in proximity to MON 88701 cotton and thus dicamba. Wild native species are likely to be impacted by dicamba, including threatened and endangered species (see below).

Runoff, Soil and Water Contamination

EPA must also critically examine the risk of runoff, soil and water contamination and the resulting increase in exposure to dicamba residue from the proposed tolerances of dicamba residue in or on cottonseed and cotton gin byproducts and the proposed use of dicamba on Monsanto's dicamba-resistant MON 88701 cotton. As EPA acknowledged in its 2006 Reregistration Eligibility Decision (RED) for dicamba, dicamba salts "rapidly convert to the free acid of dicamba," which is "very soluble and very mobile."⁷¹ The 2006 RED also concluded that dicamba "would be expected to be persistent in groundwater."⁷² Thus, runoff of dicamba could contaminate soil and groundwater sources, resulting in environmental harm in injuring non-target species and their habitats as well as increasing human health risks from exposure to dicamba. See separately-submitted CFS Science Comments for further discussion.

V. The Proposed New Use of Dicamba on Monsanto's Dicamba-Resistant MON 88701 Cotton May Affect Threatened and Endangered Species. EPA Must Consult with Expert Agencies Pursuant to Section 7 of the ESA.

Pursuant to Section 7 of the ESA, EPA has an independent duty to "insure" that Monsanto's proposed new use of dicamba on dicamba-resistant cotton will neither jeopardize any threatened or endangered species, nor harm any critical habitat, anywhere the proposed new use of dicamba may be applied.⁷³ In EPA's 2006 RED for dicamba and associated salts, the agency itself admitted that its assessment "indicate[d] that dicamba has the potential for causing risk to endangered birds, mammals, and non-target plants."⁷⁴ Despite the agency's recognition of potential threat to endangered species, EPA failed to independently determine whether the use

⁷¹ EPA, Reregistration Eligibility Decision for Dicamba and Associated Salts 14 (June 8, 2006), available at http://www.epa.gov/oppsrrd1/REDs/dicamba_red.pdf.

⁷² *Id.* at 15.

⁷³ *Wash. Toxic Coal. v. EPA*, 413 F.3d 1024, 1035 (9th Cir. 2005) (agency has burden to prove its action is non-jeopardizing.).

⁷⁴ EPA, *Reregistration Eligibility Decision for Dicamba and Associated Salts* 18 (June 8, 2006), available at http://www.epa.gov/oppsrrd1/REDs/dicamba_red.pdf.

of dicamba “may affect” any listed species or critical habitats nor consult the expert wildlife agencies as required under Section 7 of the ESA.⁷⁵

Thus, as part of its risk assessment of Monsanto’s Proposed New Use Registration Application, EPA must determine whether the proposed use of dicamba “may affect” any listed species or critical habitat; if so, EPA must consult the expert wildlife agencies (FWS and/or NMFS) in making its final decision regarding whether to register the proposed new use of dicamba.

EPA’s consultation duties under the ESA on the direct and indirect impacts of its approval action in no way vitiates the ESA duties of any other agencies (such as USDA/APHIS) for the impacts of their own approval action.

VI. EPA Must Critically Analyze the Potential Health Effects of the Proposed Dicamba Use and Proposed Tolerances of Dicamba Residue in or on Cottonseed and Cotton Gin Byproducts

EPA has a duty under the FFDCA to ensure that the proposed increase tolerance level of dicamba residue in or on cottonseed and the proposed new tolerance of dicamba residue in or on cotton gin byproducts will cause “no harm” to humans, particularly infants and children “from aggregate exposure” to dicamba.⁷⁶ The FFDCA requires that where use of a pesticide will result in any pesticide residue being left on food, EPA must either set a “tolerance” level for the amount of allowable pesticide residue that can be left on the food, or set an exemption of the tolerance requirement.⁷⁷ The tolerance or exemption requirements apply to raw agricultural commodities such as MON 88701 cotton.⁷⁸ Under the FFDCA, EPA must “establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the EPA Administrator determines that the tolerance is safe”.⁷⁹ For a tolerance level to be “safe,” the statute requires EPA determine “that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.”⁸⁰ “Aggregate exposure” includes not only dietary exposure through food consumption, but also includes “exposures through water and residential uses.”⁸¹

⁷⁵ *Id.* (“These findings are based solely on EPA’s screening level assessment and do not constitute ‘may affect’ findings under the Endangered Species Act.”).

⁷⁶ 21 U.S.C. § 346a(b)(2)(A).

⁷⁷ 21 U.S.C. § 346a(1).

⁷⁸ 21 U.S.C. § 321(r) defines “raw agricultural commodities” as “any food in its raw or natural state, including all fruits that are washed, colored or otherwise treated in their unpeeled natural form prior to marketing.”

⁷⁹ 21 U.S.C. § 342(a)(2)(A) (emphasis added); *see also* 40 C.F.R. § 180.1(f).

⁸⁰ 21 U.S.C. § 346(a)(2)(A)(ii).

⁸¹ *Natural Res. Def. Council v. Whitman*, No. C 99-03701-WHA, 2001 WL 1221774 (N.D. Cal. Nov. 7, 2001).

Human Health Risks from Dicamba

As discussed in detail in separately-submitted CFS Science Comments, human exposure to dicamba has been linked to increased major health risks such as cancer, lowered sperm counts, liver disease and Parkinson's disease.⁸² Exposure to dicamba has also been shown to have negative effects on hormonal, developmental, neurological, and immune systems.⁸³ As elaborated further below, farm workers and pesticide applicators are at the greatest risk for exposure to dicamba. For more detailed discussion of the associated human health risks under the proposed new tolerances of dicamba residue and the proposed new use of dicamba on MON 88701 cotton, see separately-submitted CFS Science Comments.

Impacts on Farmers and Pesticide Applicators

As part of its consideration of Monsanto's Dicamba New Use Registration Application and Dicamba Tolerance Petition, EPA must carefully analyze the potential health threats to farm workers and pesticide applicators. As explained above and further elaborated in separately-submitted CFS Science Comments, the vastly increased frequency of use and prolonged window of application would result in much greater exposure to dicamba, especially for farmers and pesticide applicators. In the 2006 RED for dicamba and its associated salts, EPA dismissed such health risks, concluding that:

Because dicamba is typically applied once per season and the relevant agricultural scenarios occur for only a few weeks per year, it is anticipated that dicamba exposures would be primarily short-term, and more rarely, intermediate-term.⁸⁴

However, as explained above and also in separately-submitted CFS Science Comments, the proposed use of dicamba on dicamba-resistant, MON 88701 cottons would increase the frequency of application and provide a longer window of application of the herbicide, eliminating the bases of EPA's finding regarding health risks for farm workers and pesticide applicators. Thus, in considering Monsanto's Dicamba New Use Registration Application and Dicamba Tolerance Petition, EPA must reevaluate potential health risks to farm workers and pesticide applicators from exposure to dicamba, particularly in light of the changes in use patterns of dicamba as applied on dicamba-resistant, MON 88701 cotton.

VII. EPA Must Allow a Second Opportunity for Public Comment.

In light of the new use patterns of dicamba proposed by Monsanto's Dicamba New Use Registration Application and the significant human health impacts stemming from the new tolerances of dicamba residue in or on cottonseed and cotton gin byproducts in the Dicamba Tolerance Petition, EPA should allow the public and interested parties a second opportunity to

⁸² See separate-submitted CFS Science Comments for detailed discussions and references cited therein.

⁸³ *Id.*

⁸⁴ EPA, *RED for Dicamba and its Associated Salts* 13 (June 8, 2006).

comment on Monsanto's application materials, EPA's risk assessments, and EPA's proposed registration decision on Monsanto's Dicamba New Use Registration Application and proposed tolerance determination on Monsanto's Dicamba Tolerance Petition.

The availability of Monsanto's application materials and EPA's proposed decisions is essential to ensure sufficient public notice and meaningful public participation in EPA's new use registration process. The Federal Circuit identified the following three purposes of the notice and comment: "(1) to ensure that agency regulations are tested via exposure to diverse public comment, (2) to ensure fairness to affected parties, and (3) to give affected parties an opportunity to develop evidence in the record to support their objections to the rule and thereby enhance the quality of judicial review."⁸⁵ "To achieve those purposes, ... the notice required by the APA ... must disclose in detail the thinking that has animated the form of a proposed rule and the data upon which that rule is based."⁸⁶

EPA itself recognized the importance of increased transparency and meaningful public participation in the pesticide registration process: since October 2009, the agency has implemented a new public participation process that allowed the public to "review and comment on the risk assessments and proposed registration decision ... for pesticide regulatory actions for which significant public interest is anticipated."⁸⁷ The proposed use of dicamba will enable dicamba to be used, for the first time, on cotton crops genetically engineered to resist dicamba, and significant public interest can be anticipated. Thus, EPA should allow the public to review and comment on Monsanto's application materials, the agency's risk assessments and its draft decisions prior to issuing its final registration decision on Monsanto's proposed new use registration of dicamba on dicamba-resistant MON 88701 cotton and the proposed new tolerances of dicamba residue in or on cottonseed and cotton gin byproducts.

CONCLUSION

For the above reasons, we request EPA to comply with FIFRA, FFDCA, NEPA and the ESA by critically considering the unreasonable adverse effects stemming from the change in use patterns of dicamba on dicamba-resistant MON 88701 cotton under Monsanto's Dicamba New Use Registration Application and the significant human health risks from aggregate exposure to dicamba from the proposed tolerances of dicamba residue in or on cottonseed and cotton gin byproducts requested in Monsanto's Dicamba Tolerance Petition.

⁸⁵ *Int'l Union, United Mine Workers of Am. v. Mine Safety & Health Admin.*, 407 F.3d 1250, 1259 (D.C.Cir. 2005).

⁸⁶ *Prometheus Radio Project v. FCC*, 652 F.3d 431, 449 (3d Cir. 2011) (holding, *inter alia*, that the F.C.C.'s notice of proposed rulemaking did not contain enough information about its planned overhaul to newspaper broadcast cross-ownership, or the options it was considering, to provide the public with a meaningful opportunity to comment (citing *Home Box Office, Inc. v. FCC*, 567 F.2d 9, 35–36 (D.C.Cir. 1977)) (emphasis added).

⁸⁷ EPA, *Public Involvement in Pesticide Registration*, <http://www.epa.gov/pesticides/regulating/registration-public-involvement.html> (last visited June 17, 2012).

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