Comments of Consumer Reports
On
U.S. Department of Agriculture Animal and Plant Health Inspection Service Proposed Rule
Movement of Certain Genetically Engineered Organisms
Docket No. APHIS-2018-0034

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Consumer Reports welcomes the opportunity to comment on the U.S. Department of Agriculture's (USDA) Animal and Plant Health Inspection Service's (APHIS) proposed rule on genetically engineered (GE) organisms, commonly referred to as GMOs.

Consumer Reports is an independent U.S. non-profit organization that works side by side with consumers for truth, transparency and fairness in the marketplace, through research, testing, journalism and advocacy.[1] We have more than 6 million members, and more than 1.7 million volunteers and online activists. Consumer Reports seeks to establish strong pro-consumer policies and protections to create a fairer, safer and healthier world.

Modifying the genetics of a plant through genetic engineering, including with newer technologies, such as genome editing, use of RNAi, or use of synthetic DNA, may result in useful traits but also may cause adverse environmental or human health effects due to the traits themselves or due to unintended consequences of the genetic engineering process. Consequently, all genetically engineered plants, whether produced with the older technologies or the newer technologies should be required to go through a safety assessment by USDA prior to approval. Thus, we commend USDA for saying that the newer technologies, such as genome editing and synthetic biology, are a part of genetic engineering.

However, USDA proposes to allow companies to decide for themselves, for a certain range of GE plants, whether to even come forward to USDA for approval. Companies should not be allowed to do this because it is the role of USDA to protect Americans. USDA should be making the determination that GE plants do not cause adverse environmental or human health[2] impacts during the field trial stage, not the companies. USDA also proposes to consider only whether GE plants present a plant pest risk, such as whether the GE plant will become a weed, not whether the GE plant may pose other adverse environmental or human health impacts. This

[1] www.consumerreports.org
[2] FDA has primary authority over safety of GE foods, although, in early days of GE, the environmental assessments of GE field trials usually included a section on potential health impacts.

is an excessively narrow reading of USDA's authority, and contrary to USDA's broader reading of its purview, which USDA exercised for 15 years under the Consolidated Framework for regulating GE plants adopted in 1986.[3] USDA should be making the determination that all GE plants do not cause adverse environmental or human health impacts, before they are allowed to be commercialized, as it previously did under the Consolidated Framework for 20 years.

Limiting USDA's regulatory purview to only the issue of whether a new GE plant poses a plant pest risk, and allowing companies to themselves assess safety, creates serious problems for assuring the safety of plants genetically engineered to produce pharmaceutical and industrial compounds, which USDA calls plant-made pharmaceuticals and industrials (PMPIs). Because of the risks of contamination of the food supply with drugs and chemicals from PMPIs, we urge USDA to regulate GE PMPI-producing crop plants under its noxious weed authority and to ban outdoor growing of such crop plants.

Definition of genetic engineering should include new technologies

As part of this regulation, USDA is proposing to "define *genetic engineering (GE)* as techniques that use recombinant or synthetic nucleic acids to modify or create a genome."[4] This definition would include the newer technologies such as genome editing, RNAi, production of synthetic genes, etc. As USDA notes, "This proposed definition is clearer than the existing one, which refers to modification using 'recombinant DNA techniques,' a term that is not defined in the regulations. The current definition could also be construed, contrary to our intentions, to exclude the use of synthetic DNA, *in vivo* DNA manipulation, and genome editing. "[5]

This new proposed definition is appropriate since it aligns with internationally accepted definitions and with the definition used by FDA.. The trigger for regulatory oversight should include all current and future genetic engineering technologies that either move foreign or novel DNA into the genome of a plant, or target and alter the expression of genes naturally occurring in a plant. There is global agreement, through the United Nations' food safety organization, Codex Alimentarius, that all products of "modern biotechnology"[6] should go through a safety assessment. The Codex definition of "modern biotechnology" is broad enough to include the newer techniques of genetic engineering, such as RNAi, genome editing (CRISPR-Cas 9, TALEN, ZNF, meganucleases, etc.), synthetic DNA, etc. FDA uses the Codex definition of

[3] https://www.aphis.usda.gov/brs/fedregister/coordinated_framework.pdf
[4] Pg. 26522 in https://www.govinfo.gov/content/pkg/FR-2019-06-06/pdf/2019-11704.pdf
[5] *Id.*
[6] As defined in the Codex Alimentarius publication *Principles for the Risk Analysis of Foods Derived from Modern Biotechnology* (CAC/GL 44, 2003): the application of: *i) In vitro* nucleic acid techniques, including recombinant deoxyribonucleic acid (DNA) and direct injection of nucleic acid into cells or organelles, or ii) Fusion of cells beyond the taxonomic family, that overcome natural physiological reproductive or recombinant barriers and that are not techniques used in traditional breeding and selection."

"modern biotechnology" as its definition of "bioengineering," which FDA says is a synonym for "genetic engineering."[7] Thus USDA's proposed definition of GE is consistent with the definitions used by FDA and the globally accepted Codex definition.

All GE plants should be regulated

Presently, USDA regulates GE plants "if the donor organism, recipient organism, vector, or vector agent is a plant pest or if the Administrator has reason to believe the GE organism is a plant pest."[8] Plant pests include weeds and plant diseases, which USDA has authority to prevent. Controlling plant pests is the responsibility of the USDA Animal and Plant Health Inspection Service, or APHIS. Since the vast majority of the GE plants that were developed in the first 15 years of genetic engineering use genetic material from a plant pest—such as the cauliflower mosaic virus, used as a genetic "on" switch or the Ti-plasmid from *Agrobacterium tumefaciens*, which causes crown gall disease, used as a vector to move genetic material into a host plant—most GE plants until recently have come under regulation by USDA/APHIS.

This regulatory approach however is presently resulting in exclusion of a substantial number of GE plants from USDA regulatory oversight because newer GE techniques do not utilize genetic material derived from a plant pest. Since 2011, over 80 plants have been exempted from USDA regulation because they did not contain genetic material from a plant pest and are not expected to be a plant pest.[9] Examples of such exempted plants include Kentucky bluegrass engineered to be resistant to the herbicide glyphosate, Bahiagrass engineered to be herbicide tolerant, tomatoes engineered to be virus resistant, and moss engineered to glow in the dark and release various fragrances. These are clearly GE plants and yet were not required to go through a safety assessment because they were not considered to be a plant pest risk nor to contain genetic material from a plant pest.

USDA's present proposal insures that USDA will fail to review the safety of the vast majority new GE plants. Among the adverse environmental effects that would not be evaluated are impact on pollinators and other non-target organisms, and soil microbiota in the agricultural ecosystem.

USDA states that would not even require data from field trials. This is inadequate, since field trials are the stage where unintended consequences of the genetic engineering process can be identified. USDA should require data from field trials before allowing commercialization of new GE crops.

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[7] https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-voluntary-labeling-indicating-whether-foods-have-or-have-not-been-derived

[8] Pg. 26514 in *Id.i* https://www.govinfo.gov/content/pkg/FR-2019-06-06/pdf/2019-11704.pdf

[9] https://www.aphis.usda.gov/aphis/ourfocus/biotechnology/am-i-regulated/regulated_article_letters_of_inquiry/regulated_article_letters_of_inquiry

USDA also proposes to only consider three characteristics in determining whether the GE crop poses a plant pest risk: 1) the basic biology of the plant prior to modification; 2) the trait that resulted from the genetic modification; and 3) the method of action (MOA) of the trait.

In addition, USDA, in certain circumstances, would allow the companies to decide for themselves whether they are exempted from regulation. USDA says that it would exempt GE plants with a plant-trait-mechanism of action that has already been evaluated by USDA and determined to not pose a plant pest risk. USDA defines trait as "an observable (able to be seen or otherwise identified) characteristic of an organism" and mechanism of action as the "biochemical process(es) through which genetic material determines a trait."[10] These definitions could be interpreted very broadly. The example given in the FR notice states: "For example, the trait of coleopteran resistance can result from either of at least two MOAs: Expression of Cry protein, or expression of a silencing complex targeting ribonucleic acids (RNA)."[11] Note that the trait is "coleopteran resistance" so it could mean resistance to any beetles species, rather than a specific pest, such as the Colorado potato beetle. Second, note that one MOA for coleopteran resistance is "Cry protein" without specifying a particular Cry protein. From these two examples, it's clear that this "plant-trait-MOA combination" is so broad such that ANY Cry protein (we know there are dozens of them[12], and that would also include new synthetic or optimized Cry proteins) that targets any lepidopteran pest or any coleopteran pest (there are potentially hundreds of butterfly, moth and beetle pests), could be inserted into any plant that has already been engineered with any trait, without coming to USDA. Exempting all plants engineered with Cry proteins that target lepidopteran or coleopteran pests from USDA oversight is problematical since it is known that engineering plants with multiple Bt Cry proteins could have synergistic effects that would need to be investigated as they could have effects not only on the targeted lepidopteran and/or beetle pest, but also on non-target organisms that are lepidopterans or coleopterans.[13]

We urge USDA to require that all GE plants go through a regulatory process and assessed for their potential environmental and human health impacts, not just whether they pose a plant pest risk.

Drug and industrial chemical-producing food or feed plants must be regulated and prohibited for outdoor production

A major part of this deregulatory proposal is that USDA will only consider whether the GE plant will become a plant pest and does not consider other environmental or human health impacts. This

[10] Pg. 26517 in https://www.govinfo.gov/content/pkg/FR-2019-06-06/pdf/2019-11704.pdf.
[11] Pg. 26526 in *Id.*
[12] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4280536/pdf/toxins-06-03296.pdf
[13] https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0835-0043

approach creates significant public health risks related to development and commercialization of plants that have been engineered to produce pharmaceutical or industrial compounds. USDA refers to such plants as genetically engineered (GE) plant-made pharmaceutical and industrial (PMPI)-producing plants and acknowledges that such GE PMPI-producing plants could raise safety issues for both human food and animal feed as a result of contamination which would not be considered under these proposed regulations. USDA acknowledges that some federal oversight of such plants may be warranted: "Federal oversight of outdoor plantings of PMPI-producing plants could be necessary to prevent the unlawful introduction into the human and animal food supply of pharmaceutical or industrial PMPI products, even when the principal purpose of the plants is not for human or animal food use. In addition to potential adulteration issues (such as the potential of an unapproved food additive and other food safety risks) posed by such plants should they enter the food supply, a gap in Federal oversight could generate concerns from the general public regarding the safety and wholesomeness of the human or animal food supply, which could adversely impact agricultural interests."[14]

USDA also acknowledges that such plants would not be regulated under this proposal, since they are not plant pests, and so could be grown outdoors: "there is a likelihood that most, if not all, GE PMPI-producing plants that are currently under APHIS permits could be determined to be not regulated under the provisions of the proposed regulations after a regulatory status review because they are unlikely to pose a plant pest risk. Thus, such plants could be grown outdoors without the need for APHIS permits and without APHIS oversight."[15]

Furthermore, USDA recognizes that, unlike USDA, neither the Environmental Protection Agency (EPA) nor the Food and Drug Administration (FDA) have adequate regulations to deal with these plants, noting that "One of the reasons APHIS' oversight of such crops has been an important part of the coordinated framework for oversight of GE plants is that companies are not necessarily required to notify FDA or EPA when the developer of plants PMPI-producing plants."[16]

There are reasons to be concerned about the potential for contamination from PMPI-producing plants. By 2005, there had been more than 300 open air field trials of such GE PMPI-producing plants. Most of the trials involved food plants—corn, rice and soybeans—and tobacco.[17]

USDA's current oversight of field trials and commercialization of such crops should be expanded, not eliminated. While USDA has said companies must have a permit to conduct research trials for drug-producing plants, and lists such trials on a website, almost all the information about the trials, including their location, the substance(s) being produced, and the plant being grown, usually are withheld as confidential business information (CBI). Even the size of the test site is sometimes treated as confidential. Not knowing all the drug and industrial compounds that have been engineered into a plant, or only knowing the identity of a few compounds, makes it significantly harder to give meaningful input on such trials. It also makes it

[14] Pg. 26518 in https://www.govinfo.gov/content/pkg/FR-2019-06-06/pdf/2019-11704.pdf
[15] *Id.*
[16] *Id.*
[17] http://www.gepolicyalliance.org/hhsue/2014/09/foe_pharma.pdf

harder to identify and trace back any contamination problem. Also, not knowing the exact locations of the specific field trials for the GE PMPI-producing plants makes oversight more difficult and could increase the potential problem of contamination of food plants with these GE PMPI-producing plants.

"Escape" of such plants from field trials and contamination of food crops is not just a theoretical problem. It has already occurred. In late 2002, the USDA and FDA made public the discovery of problems of contamination of food crops from two ProdiGene[18] field trials involving corn engineered to produce various pharmaceuticals, one in Iowa in September and one in Nebraska in October.

In Iowa, according to the USDA, the corn engineered to produce pharmaceuticals came up spontaneously in a soybean field a year after it was planted ("volunteer" corn) and may also have sprouted in a nearby cornfield. As a result, the government ordered ProdiGene to burn 155 acres of contaminated and potentially contaminated crops.[19] In Nebraska, volunteer corn plants from a test conducted in 2001 contaminated soybeans being grown in the same field in 2002 and, as a result, 500,000 bushels of soybeans worth $2.7 million[20] were hauled away and destroyed by USDA at a cost of $3.5 million. USDA gave ProdiGene two years interest-free to pay the government back.[21] USDA also fined ProdiGene $250,000 for these problems.[22]

As a result of the two ProdiGene contamination incidents, major parts of the food industry came out strongly against the use of food crops for production of pharmaceuticals and industrial compounds unless there are stringent regulations that can guarantee that contamination of food and feed crops does not occur. The National Food Processors Association, in comments submitted to FDA in February 2003, "strongly urged that there be no use of food or feed crops to produce plant-made pharmaceuticals (PMPs) or industrial chemicals 'without a 100% guarantee against any contamination of the food or feed supply.' … if the food industry had complete control of this promising technology from the beginning, we would never have supported the use of food or feed crops for the production of PMPs. The risk of contamination is just too great."[23] The Grocery Manufacturers of America and nine other food and restaurant organizations[24] submitted comments to FDA that called for a moratorium on field trials of PMPs until stringent regulation could be put in place.[25]

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[18] Prodigene Inc. was a small biotechnology company experimenting with corn engineered with a range of drugs and industrial compounds, including aids vaccine, blood-clotting drug, digestive enzyme, and a vaccine for the pig disease transmissible gastroenteritis. According to ProdiGene, both trials involved corn engineered to produce a pig vaccine. The FDA, however, put out a press statement saying that in the Nebraska case, a human drug had been engineered into the corn.

[19] https://www.apnews.com/28696ce2e1f10824fad6ed1f0e406822

[20] *Id.*

[21] https://www.sfgate.com/science/article/GMO-experiments-receive-questionable-oversight-5740478.php

[22] https://www.wsj.com/articles/SB10392121116081823353

[23] https://www.cabi.org/agbiotechnet/news/2278

[24] the American Bakers Association, the Biscuit & Cracker Manufacturers Association, the Food Marketing Institute, the Institute of Shortening & Edible Oils, the International Dairy Foods Association, the National Confectioners Association, the National Council of Chain Restaurants, the National Restaurant Association, and the National Soft Drink Association.

[25] http://www.gene.ch/genet/2003/Feb/msg00045.html

ProdiGene's problems continued. In 2004, the year after planting one of ProdiGene's GE corn field sites in Nebraska, GE corn volunteers were found in a nearby sorghum field and may have also contaminated a nearby oat field that had already been harvested for animal feed. In 2007, USDA fined ProdiGene a small $3,500 fine but got the company to agree that neither it nor "its successors in interest" would ever again apply to USDA to introduce GE plants into the environment.[26]

Another case of contamination occurred with GE Enogen corn, which is designed to enhance production of ethanol for biofuels use. Enogen corn is engineered to produce high levels of alpha-amylase which converts starches in corn to sugar, the first step in making corn ethanol. Even low levels of contamination of food-grade corn with Enogen (1 kernel out of 10,000) would make the food corn unfit for many foods, including corn chips, cereals and tamales, since starches give some of the stiffness and pliability to corn products, and low starch levels could lead to crumbly corn chips, limp cereal or gooey tamales. USDA allowed Enogen for commercial use, officially deregulating it, in 2011, but was opposed by the Corn Refiners Association,[27] National Grain and Feed Association, the North American Export Grain Association, the North American Millers Association and the Pet Food Institute[28] due to the potential problem of contamination of food-grade corn. Syngenta, the developer of Enogen corn, said that it would be managed in a "closed loop" production process that would prevent contamination of food grade corn.

In 2017, *The Organic & Non-GMO Report* reported that Enogen corn was found to have contaminated a significant amount of non-GMO white corn in Nebraska that is used to make flour for tortillas and other products leading to substantial losses to white corn growers.[29] In addition, some 120,000 pounds of white corn sent to a California company appeared to have been contaminated with Enogen corn, since the tamales made with this corn flour were gooey and fell apart, traits that are consistent with contamination with alpha-amylase; some people even reported being sick after eating these tamales.[30]

Given these reported problems with GE PMPI-producing plants, we are concerned that USDA's proposed new regulation of GE crops would leave GE-PMPI-producing plants with no regulatory oversight, not even the limited oversight APHIS currently uses, e.g., 7 CFR part 340- which talks about the presence of plant pest DNA or possibility of becoming a plant pest. We think that USDA could use their noxious weed authority, e.g., 7 CFR 360, to regulate these plants, since they contain "plant products" that meet the Plant Pest Act's definition of noxious weeds as potentially hazardous products. Under USDA's noxious weed authority, USDA can look not only at potential environmental and human toxicity hazard of a noxious weed, but can

[26] https://www.sfgate.com/science/article/GMO-experiments-receive-questionable-oversight-5740478.php
[27] https://www.regulations.gov/document?D=APHIS-2007-0016-0293
[28] https://www.regulations.gov/document?D=APHIS-2007-0016-0271
[29] https://non-gmoreport.com/articles/gmo-ethanol-corn-contamination-raises-concerns-another-starlink-disaster/
[30] *Id.*

also consider potential economic effects as well, such as the potential economic implications of contamination of food-grade crops with drug and industrial compounds. USDA should use the noxious weed authority to prohibit the outdoor cultivation of all GE PMPI-producing plants if the host plants have food or feed uses. If the host plant is not a food or feed plant, APHIS must rigorously assess the potential for the PMPI-producing plant to contaminate the food/feed supply, and prohibit or restrict cultivation as needed to prevent it.

Conclusion

In conclusion, although GE plants hold out promise for improving crops, this new technology also raises environmental and health questions that should require premarket assessment by USDA before the crops are allowed on the market. We commend USDA for their proposed definition of genetic engineering since it includes the newer technologies such as genome editing, RNAi, use of synthetic DNA, etc. We urge USDA to require that all GE plants, not just plants posing a plant pest risk, go through a regulatory process and assessed for their potential environmental and human health impacts. Finally, USDA should use its noxious weed authority to regulate field trials and commercialization of all PMPIs and prohibit the outdoor cultivation of all GE PMPI-producing plants if the host plants have food or feed uses. If the host plant is not a food or feed plant, APHIS must rigorously assess the potential for the PMPI-producing plant to contaminate the food/feed supply, and prohibit or restrict cultivation as needed to prevent it.