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12
13 **THE UNITED STATES DISTRICT COURT**
14 **FOR THE NORTHERN DISTRICT OF CALIFORNIA**

15
16 CENTER FOR FOOD SAFETY and CENTER)
FOR ENVIRONMENTAL HEALTH,)
17)
18 *Plaintiffs,*)

19 v.)

20 SONNY PERDUE, Secretary of the United)
States Department of Agriculture; BRUCE)
21 SUMMERS, Administrator of the Agricultural)
Marketing Service; and the UNITED STATES)
22 DEPARTMENT OF AGRICULTURE,)
23)
24 *Defendants.*)

Case No.18-cv-4633-EDL

**PLAINTIFFS' MOTION FOR
SUMMARY JUDGMENT**

Date: October 16, 2018
Time: 9:00 a.m.
Courtroom: E – 15th Floor
Hon. Elizabeth D. Laporte

NOTICE OF MOTION AND MOTION FOR SUMMARY JUDGMENT

PLEASE TAKE NOTICE that on October 16, 2018, at 9:00 a.m., or as soon thereafter as counsel may be heard, Plaintiffs Center for Food Safety and Center for Environmental Health, by and through their undersigned counsel, will bring for hearing their Motion for Summary Judgment in the Courtroom of the Honorable Elizabeth D. Laporte, United States Magistrate Judge, U.S. District Court for the Northern District of California, San Francisco Division, Courtroom E - 15th Floor, 450 Golden Gate Avenue, San Francisco, California 94102.

Pursuant to Local Rules 7-2 and 7-3, and 56, Plaintiffs hereby move for summary judgment on their sole cause of action, the unlawful withholding of the regulations for the labeling of genetically engineered foods under the Federal Bioengineered Food Disclosure Standards Act, Pub. L. No. 114-214, 130 Stat. 834 (2016), Congressionally-mandated by July 29, 2018. Although Defendants, Sonny Perdue, Secretary of the United States Department of Agriculture; Bruce Summers, Administrator of the Agricultural Marketing Service; and the United States Department of Agriculture, have not yet filed an answer to Plaintiffs' complaint, Plaintiffs are entitled to summary judgment on their sole claim pursuant to Fed. R. Civ. P. 56(b) (providing that "[u]nless a different time is set by local rule or the court orders otherwise, a party may file a motion for summary judgment at any time until 30 days after the close of all discovery"). *See Holtzman v. Richardson*, 361 F.Supp. 544, 548 (E.D.N.Y. 1973) (the 1946 Rule 56 amendment "permitted a motion for summary judgment in advance of answer" and "should be interpreted in a manner to expedite the disposition of litigation."). Pre-answer motions for summary judgment are particularly appropriate "where the only question involved is one of law." *Sec. Tr. Co. of Rochester, N.Y., v. Woodward*, 73 F. Supp. 667, 671 (S.D.N.Y. 1947). Here, the sole count is a question of law: whether Defendants failed to meet a mandatory statutory deadline. Plaintiffs are entitled to summary judgment because Defendants failed to issue final regulations implementing the mandatory federal standards for "bioengineered" or genetically engineered food disclosure by the express deadline, and have violated the Federal Bioengineered Food Disclosure Standards Act and the Administrative Procedure Act, 5 U.S.C. § 706(1).

1 Plaintiffs are entitled to judgment as a matter of law for this unlawful withholding, and seek
2 injunctive and declaratory relief compelling the Defendants to promulgate its genetically
3 engineered (GE) food disclosure standard by a date certain, under a Court-ordered timetable for
4 completion.

5 In support of this Motion, Plaintiffs rely upon the attached Memorandum of
6 Points and Authorities, Plaintiffs' Complaint, documents referenced in Plaintiffs'
7 Complaint, and matters subject to judicial notice.

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INTRODUCTION

1
2 This is an important case, but a relatively straightforward one. Plaintiffs, two non-profit
3 public interest organizations, challenge Defendants United States Department of Agriculture
4 (USDA) and Agricultural Marketing Service (collectively, USDA or Defendants) failure to
5 promulgate genetically engineered (GE) food labeling regulations by the mandatory deadline set
6 in the Federal Bioengineered Food Disclosure Standards Act (hereinafter the “GE Labeling Act”
7 or “the Act”), Pub. L. No. 114-214, 130 Stat. 834 (2016). Congress enacted the GE Labeling Act
8 to provide Americans with the information they need to make informed food decisions by setting
9 a nationwide “bioengineered,” or GE, food disclosure standard. The regulations are so critical
10 that Congress required them promulgated by an express statutory deadline, a rare legislative
11 command. Recognizing that states were beginning to require mandatory GE food labeling on
12 their own, Congress also preempted state laws requiring GE labeling in favor of a federal
13 standard; but until USDA issues the regulations, the statute is an empty vessel and the American
14 people are left without any information on whether their food is genetically engineered.

15 Plaintiffs seek summary judgment that USDA violated the GE Labeling Act and the
16 Administrative Procedure Act (APA), 5 U.S.C. § 701 *et seq.* This case is particularly well-suited
17 for summary judgment, because there is only one undisputed material fact: that USDA failed to
18 comply with the Act’s deadline. USDA has therefore unlawfully withheld action that it was
19 required to take: issuing regulations by a date certain that has now lapsed. No other facts are
20 material because, in this Circuit, if an agency fails to comply with an express statutory deadline,
21 it has *per se* violated the law. *See, e.g., Biodiversity Legal Found. v. Badgley*, 309 F.3d 1166,
22 1177-78 & n.11 (9th Cir. 2002).

23 Relief is similarly straightforward. In these instances, the APA and this Court’s precedent
24 requires that the Court compel agency action unlawfully withheld. 5 U.S.C. § 706(1);
25 *Biodiversity Legal Found.*, 309 F.3d at 1177. Thus, the Court should order USDA to promulgate
26 its GE food disclosure standard by a date certain, under a Court-ordered timetable for
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1 completion. Accordingly, Plaintiffs respectfully move for summary judgment and relief
 2 compelling Defendants' unlawfully withheld action.¹

3 **STATUTORY AND REGULATORY FRAMEWORK**

4 The GE Labeling Act, the first federal law to establish a nationwide system requiring
 5 disclosure of GE foods, went into effect July 29, 2016. The Act's purpose is to provide
 6 Americans with the information they need to make informed food decisions by setting a
 7 nationwide "bioengineered," or GE, food disclosure standard. The Act commands that "not later
 8 than 2 years after July 29, 2016, the Secretary shall establish a national mandatory bioengineered
 9 food disclosure standard with respect to any bioengineered food and any food that may be
 10 bioengineered; and establish such requirements and procedures as the Secretary determines
 11 necessary to carry out the standard." 7 U.S.C. § 1639b(a).

12 While Congress established basic standards, it left much of the detail for USDA to set up
 13 in its implementing regulations. *See* 7 U.S.C. §§ 1639b(b); (d). Congress also established
 14 recordkeeping requirements and empowered USDA to examine and audit persons subject to the
 15 mandatory disclosure requirement. *See* 7 U.S.C. § 1639b(g). Congress further required that
 16 USDA conduct a study to measure the efficacy of electronic or digital disclosures in
 17 accomplishing the goals of the Act. *See* 7 U.S.C. § 1639b(c). Finally, Congress expressly
 18 preempted state laws requiring GE labeling. *See* 7 U.S.C. § 1639b(e).

19
 20 ¹ Plaintiffs have standing because they have (1) suffered injury (2) traceable to USDA's
 21 challenged conduct that is (3) redressable. *See, e.g., Friends of the Earth v. Laidlaw Envtl.*
 22 *Servs.*, 528 U.S. 167, 180-81 (2000); *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560 (1992).
 23 CFS has over 950,000 members nationwide, including thousands in states like Vermont, which
 24 passed a mandatory GE labeling law that went into effect in July 2016, before the GE Labeling
 25 Act preempted state labeling laws. Compl., ECF No. 1 ¶ 15. CEH similarly has members that
 26 have an interest in securing transparency on food products, including whether they are GE, to
 27 know what they are feeding their families. *Id.* ¶ 19. These members have waited decades for
 28 disclosure of whether the food they buy is genetically engineered, through clear, on-package
 labeling like that enjoyed by residents of 64 other nations around the world. *Id.* ¶¶ 18, 20. These
 members want to know whether food is GE for health, personal, economic, environmental,
 religious, and/or cultural reasons, and as such, the failure of USDA to timely promulgate rules to
 require the labeling of GE foods harms CFS and CEH members' same interests. *Id.* ¶¶ 59-63.

FACTUAL BACKGROUND

1
2 Sixty-four countries, including Japan, South Korea, China, Australia, Russia, India, the
3 European Union member states, and other key U.S. trading partners, already have laws
4 mandating labeling of GE foods.² Although the U.S. approved the first GE crops in the 1990s,³
5 U.S. consumers are still awaiting mandatory GE disclosure on food labels. Mandatory labeling is
6 necessary to ensure that consumers are fully and reliably informed about the products they
7 purchase and consume. Such labels provide informed consent, and prevent consumer deception
8 or misleading labeling by omission. Polls consistently show that the overwhelming majority of
9 Americans want to know whether their food has been genetically engineered or contains GE
10 ingredients.⁴

11 People want to know if food is produced using GE for numerous reasons: health,
12 personal, economic, environmental, religious, and cultural. For example, on the human health
13 side, the public knows that the Food and Drug Administration (FDA), the Agency charged with
14 ensuring the safety of most foods, does not actually independently test the food safety of GE
15 foods or require them to be tested.⁵ FDA does not “approve” GE foods for safety; rather, the
16 Agency has confidential meetings with industry in which it merely reviews the industry’s own
17 testing—and even that is only voluntary.⁶ Market entry for GE foods is based solely on
18 confidential industry research.⁷

19
20 ² Ctr. for Food Safety, *International Labeling Laws*,
<https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/international-labeling-laws>
21 (last accessed Sept. 5, 2018).

22 ³ Natasha Gilbert, *GM crop escapes into the American wild*, *Nature*,
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23 ⁴ Ctr. for Food Safety, *U.S. Polls on GE Food Labeling*,
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24 (last accessed Sept. 5, 2018).

25 ⁵ Ctr. for Food Safety, *About GE Food Labeling*,
<https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/about-ge-labeling> (last
26 accessed Sept. 5, 2018).

27 ⁶ *Id.*

28 ⁷ *Id.*

1 Scientific studies have shown that genetic engineering of plants and animals can and has
2 caused unintended consequences.⁸ Manipulating genes via genetic engineering and inserting
3 them into organisms is an imprecise process.⁹ The results are not always predictable or
4 controllable. Mixing plant, animal, bacterial, and viral genes through genetic engineering, in
5 combinations that cannot occur in nature, can produce results that lead to adverse health or
6 environmental consequences.¹⁰

7 U.S. government scientists have stated that the artificial insertion of genetic material into
8 plants via genetic engineering can cause a variety of significant problems with plant foods. Such
9 genetic engineering may have consequential health concerns such as an increase in the levels of
10 known toxicants and food allergens or the creation of new toxicants and food allergens.¹¹

11 Further, industry restrictions prohibit independent scientists from conducting safety and
12 risk-assessments of GE materials used in food products.¹² There are no long-term or
13 epidemiological studies in the U.S. examining whether GE foods are safe for human
14 consumption.¹³ Without GE labeling, there is no accountability or traceability to link such foods
15 to proliferating public health problems. Mandatory labeling of GE foods can provide a method

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17 ⁸ Ctr. for Food Safety, *GE Food & Your Health*,
18 <https://www.centerforfoodsafety.org/issues/311/ge-foods/ge-food-and-your-health> (last accessed
19 Sept. 5, 2018).

19 ⁹ Behrokh Mohajer Maghari and Ali M. Ardekani, *Genetically Modified Foods and Social*
20 *Concerns*, *Avicenna Journal of Medical Biotechnology*, v.3(3); July-Sept. 2011,
21 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3558185/>.

20 ¹⁰ Ctr. for Food Safety, *About Genetically Engineered Foods*,
21 <https://www.centerforfoodsafety.org/issues/311/ge-foods/about-ge-foods> (last accessed Sept. 5,
22 2018).

22 ¹¹ *Supra* n.8; William Freese & David Schubert, *Safety Testing and Regulation of Genetically*
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24 [https://www.centerforfoodsafety.org/files/freese_safetytestingandregulationofgeneticallyengineer
25 edfoods_nov212004_62269.pdf](https://www.centerforfoodsafety.org/files/freese_safetytestingandregulationofgeneticallyengineeredfoods_nov212004_62269.pdf).

24 ¹² *Do See Companies Control Crop Research?*, *Scientific American*, Aug. 1, 2009,
25 <https://www.scientificamerican.com/article/do-seed-companies-control-gm-crop-research/>.

25 ¹³ Ctr. for Food Safety, *Myths & Realities of GE Crops*,
26 <https://www.centerforfoodsafety.org/issues/311/ge-foods/myths-and-realities-of-ge-crops> (last
27 accessed Sept. 5, 2018).

1 for detecting, on a large epidemiological scale, the potential health effects of consuming such
2 foods.¹⁴ These facts rightly give consumers pause; disclosure through labeling allows them to
3 make their own choices about whether to buy and consume GE foods.

4 Additionally, consumers want the ability to make purchase decisions that align with their
5 values. On the environmental side, GE crops are a key cog of inherently unsustainable industrial
6 agriculture, and cause significant adverse environmental impacts. GE crops are essentially a
7 pesticide-promoting technology: The overwhelming majority of commercial GE crops are
8 genetically engineered by pesticide companies, such as Monsanto, Dow Chemical, and Bayer
9 (now the owner of Monsanto), to withstand herbicide application (with their pesticide products)
10 or to produce their own pesticides. Consequently, these GE crops have dramatically increased
11 the overall pesticide output of American agriculture into our environment. Monsanto's GE crops,
12 "Roundup Ready" crops resistant to glyphosate, have made glyphosate the most used pesticide in
13 history, with an almost fifteen-fold increase globally since 1996 and two-thirds of the total U.S.
14 application volume from 1974-2014 was sprayed in the last decade.¹⁵ Reliance on these
15 pesticide-promoting GE crop systems has caused a number of harms, including widespread
16 pollution of our waterways and native ecosystems, injury to beneficial insects such as
17 pollinators, and harm to soil health.¹⁶ The well-established environmental impacts of GE crops
18 (and their attendant pesticides) are widespread and dire. People reasonably want to align their
19 food purchasing choices with their environmental values.

20 Protection of the environment and protection of public health are intimately intertwined.
21 In 2015, the World Health Organization's International Agency for Research on Cancer

22 ¹⁴ Philip J. Landrigan, M.D., and Charles Benbrook, Ph.D., *GMOs, Herbicides, and Public*
23 *Health*, New England Journal of Medicine (2015), [http://www.nejm.org/doi/full/10.1056/](http://www.nejm.org/doi/full/10.1056/NEJMp1505660#t=article)
24 [NEJMp1505660#t=article](http://www.nejm.org/doi/full/10.1056/NEJMp1505660#t=article).

25 ¹⁵ Charles M. Benbrook, *Trends in glyphosate herbicide use in the United States and globally*,
26 *Environ. Sci. Eur.* (2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5044953/>.

27 ¹⁶ Charles Benbrook, *Impacts of Genetically Engineered Crops on Pesticide Use in the United*
28 *States: The First Thirteen Years*, The Organic Center, Nov. 2009, [https://www.organic-](https://www.organic-center.org/reportfiles/13Years20091126_FullReport.pdf)
[center.org/reportfiles/13Years20091126_FullReport.pdf](https://www.organic-center.org/reportfiles/13Years20091126_FullReport.pdf).

1 concluded that glyphosate is probably carcinogenic to humans.¹⁷ Evidence unearthed in a recent
2 case in this district shows the willingness of the agrochemical industry to engage in morally
3 objectionable tactics to downplay potential carcinogenic effects of glyphosate.¹⁸ Disturbingly,
4 studies show that the probably-carcinogenic glyphosate contaminates drinking water sources
5 worldwide, especially in agricultural regions.¹⁹

6 On the agricultural side, GE crops have harmed America's traditional and conventional
7 farmers: over the past decade transgenic contamination of traditional crops from GE crops has
8 caused U.S. farmers billions of dollars in market losses.²⁰ Numerous foreign markets with
9 restrictions on genetically engineered foods have restricted imports of U.S. crops due to concerns
10 about such forms of production.²¹ Some foreign markets are purchasing agricultural products
11 from countries other than the U.S., because the U.S. does not identify GE crops, making it
12 impossible for buyers to determine whether products meet their national labeling laws or
13 restrictions.

14 Further, the widespread adoption of crops engineered for pesticide resistance has
15 proliferated an epidemic of resistant "superweeds" now covering more than seventy million acres

16
17 ¹⁷ Daniel Cressey, *Widely used herbicide linked to cancer*, Nature, Mar. 24, 2015,
<https://www.nature.com/news/widely-used-herbicide-linked-to-cancer-1.17181>.

18 ¹⁸ On August 10, 2018, a jury found that Monsanto "acted with malice or oppression" in failing
19 to warn DeWayne Johnson, a school groundskeeper with terminal cancer, about the risks of
20 exposure to glyphosate and awarded him \$289 million in damages. Sam Levin, *Monsanto
ordered to pay \$289m as jury rules weedkiller caused man's cancer*, The Guardian, Aug. 11,
2018, <https://www.theguardian.com/business/2018/aug/10/monsanto-trial-cancer-dewayne-johnson-ruling>.

21 ¹⁹ See e.g., Myers, J. P., Antoniou, M. N., Blumberg, B., Carroll, L., Colborn, T., Everett, L. G.,
22 Hansen, M., Landrigan, P. J., Lanphear, B. P., Mesnage, R., Vandenberg, L. N., vom Saal, F. S.,
23 Welshons, W. V., and Benbrook, C. M., *Concerns over use of glyphosate-based herbicides and
risks associated with exposures: A consensus statement*. Environmental Health Environ Health
24 (2016), <https://ehjournal.biomedcentral.com/articles/10.1186/s12940-016-0117-0>.

25 ²⁰ Chelsea Harvey, *Around the country, organic farmers are pushing for 'GE-free' zones*, The
26 Washington Post, Jan. 4, 2016, https://www.washingtonpost.com/news/energy-environment/wp/2016/01/04/around-the-country-organic-farmers-are-pushing-for-ge-free-zones/?utm_term=.df74088fdc31.

27 ²¹ *Id.*

1 of U.S. farmland.²² These weeds have flourished, infesting farm fields and roadsides,
2 complicating weed control for farmers, and forcing farmers to resort to more and increasingly
3 toxic pesticides.²³ Many consumers do not want to support unsustainable agricultural practices
4 that harm American farmers and instead want to make choices that align with their support of
5 family farmers, not multinational agrochemical companies.

6 Juxtaposed against these facts, the U.S. public is discovering that the industry's hype
7 about genetically engineered foods is false: Despite billions of dollars in research and nearly two
8 decades of commercialization, there are no GE crops commercially produced to increase yields,
9 reduce world hunger, or mitigate global warming.²⁴ Rather, the commercial reality is that
10 agrochemical companies have largely succeeded in engineering these crops to be resistant to the
11 companies' own products—pesticides—in order to reap huge profits.²⁵

12 Studies show that, due to the lack of mandatory labeling, many American consumers are
13 under an incorrect assumption as to whether the food they purchase is produced with GE.²⁶
14 Disclosure of whether or not foods are genetically engineered will reduce this consumer
15 confusion and deception.

16 Consumers also want mandatory labeling for religious, cultural, ethical, moral, personal,
17 or dietary reasons.²⁷ Without mandatory disclosures, consumers of GE foods may unknowingly

18 ²² Donnelle Eller, *'Superweeds' choke farms*, Des Moines Register, June 21, 2014,
19 [https://www.desmoinesregister.com/story/money/agriculture/2014/06/22/superweeds-choke-](https://www.desmoinesregister.com/story/money/agriculture/2014/06/22/superweeds-choke-farms/11231231/)
20 [farms/11231231/](https://www.desmoinesregister.com/story/money/agriculture/2014/06/22/superweeds-choke-farms/11231231/).

21 ²³ *Seed Giants vs. U.S. Farmers*, Center for Food Safety & Save Our Seeds, 2013, at 10,
22 https://www.centerforfoodsafety.org/files/seed-giants_final_04424.pdf.

23 ²⁴ *Who benefits from GM crops?*, Friends of the Earth International, Jan. 2008, at 7, 39,
24 [https://www.centerforfoodsafety.org/files/foe-i-who-benefits-2008--full-report-final-2-6-](https://www.centerforfoodsafety.org/files/foe-i-who-benefits-2008--full-report-final-2-6-08_51613.pdf)
25 [08_51613.pdf](https://www.centerforfoodsafety.org/files/foe-i-who-benefits-2008--full-report-final-2-6-08_51613.pdf).

26 ²⁵ *Id.* at 7, 40.

27 ²⁶ Sandy Skrovan, *Consumers are confused about 'organic' and 'non-GMO' labels*, Food Dive,
28 Oct. 30, 2017, [https://www.fooddive.com/news/consumers-are-confused-about-organic-and-non-](https://www.fooddive.com/news/consumers-are-confused-about-organic-and-non-gmo-labels/508409/)
29 [gmo-labels/508409/](https://www.fooddive.com/news/consumers-are-confused-about-organic-and-non-gmo-labels/508409/) (last accessed Sept. 5, 2018).

30 ²⁷ Ctr. for Food Safety, *About GE Food Labeling*,
31 <https://www.centerforfoodsafety.org/issues/976/ge-food-labeling/about-ge-labeling> (last
32 accessed Sept. 5, 2018).

1 violate their beliefs or health restrictions. Labeling will provide consumers with the information
2 they need to make safe and informed decisions.

3 **PROCEDURAL HISTORY**

4 President Obama signed the GE Labeling Act into law on July 29, 2016. The primary
5 goals of the Act are to “(1) establish a national mandatory bioengineered food disclosure
6 standard with respect to any bioengineered food and any food that may be bioengineered; and (2)
7 establish such requirements and procedures as the Secretary determines necessary to carry out
8 the standard.” 7 U.S.C. § 1639b(a).

9 Prior to drafting a proposed rule, USDA presented the public with 30 questions pertaining
10 to mandatory GE food labeling as a means of collecting stakeholder opinions. The questions
11 covered a range of topics such as terminology, definitions, threshold, and scope. USDA posted
12 these questions on its website and collected public input from June 28, 2017 through August 25,
13 2017. USDA received comments from over 112,000 concerned citizens and organizations. In
14 July 2017, Plaintiffs submitted detailed comments to USDA on the scoping “30 questions”
15 notice.

16 Additionally, the statute requires that USDA conduct a study to inform its rulemaking.
17 The required study concerns one of the most controversial aspects of the Act: the potential to
18 allow food companies to use “digital or electronic” disclosures for GE foods, such as QR codes
19 that must be scanned with a smartphone. Correctly recognizing how unprecedented and
20 controversial this potential option was, Congress mandated that USDA first specifically study the
21 efficacy, or lack thereof, of this type of disclosure and its impacts on consumers and retailers.
22 The Act mandated the study analyze, among other things, the “potential technological challenges
23 that may impact whether consumers would have access to the bioengineering disclosure through
24 electronic or digital disclosure methods,” before the statutorily imposed deadline of July 29,
25 2017. *Id.* § 1639b(c)(1). This study was included in the Act to measure the efficacy of the
26 electronic/digital link option in accomplishing the goals of the Act.

1 The Act also required public consultation on the study stating, “[i]n conducting the study
2 under paragraph (1), the Secretary shall solicit and consider comments from the public.” *Id.* §
3 1639b(c)(2). Public comment was necessary to allow for successful understanding of consumer
4 behavior.

5 *The Missed Study Deadline and Subsequent Litigation*

6 USDA failed to finish and publicly release the study by the statutory deadline. USDA
7 also failed to hold public comment on the study by the statutory deadline. Because the study was
8 necessary to inform USDA’s ultimate rulemaking decision and what type of disclosure is
9 mandated, CFS and its members were injured by their inability to review and participate in the
10 mandated study and public comment process. USDA’s withholding of the 2017 study negated
11 CFS and its members’ procedural rights to participate in the implementation of the GE Labeling
12 Act. Accordingly, CFS filed suit pursuant to the APA against USDA, for its failure to comply
13 with the Act’s deadline. *Ctr. for Food Safety v. Perdue, et al.*, No. 17-cv-04967-JSW (N.D. Cal.
14 2017). Shortly thereafter USDA publicly released the study and agreed to hold comment on it,
15 mooted the case, which Plaintiffs’ then voluntarily dismissed.

16 It is unknown why USDA did not release the 2017 study until forced to do so through
17 litigation. It is very likely because the study is not at all supportive of the use of electronic or
18 digital forms of GE food disclosure. Among other relevant findings, all of which go to the factors
19 specifically enumerated by Congress in the Act, the study concluded that technological
20 challenges, such as lack of technical knowledge, prevent consumers from acquiring the necessary
21 GE information via methods of digital disclosure, like QR codes. The study found further
22 obstacles, such as lack of consumer association between digital links and additional food content
23 information. The study found that 100% of consumers polled did not recognize digital links were
24 associated with food information. Additionally, the study found the use of digital disclosure to be
25 inimical to various populations such as those sixty-five years of age and older as well as those
26 living in rural communities. This is due to the disparate rates of smartphone ownership across
27

1 varying demographics. The complete study, containing additional examples of the inefficacy of
2 digital disclosure, can be found on USDA's website.²⁸

3 As these non-exhaustive examples show, the 2017 study found significant problems with
4 the efficacy of digital and electronic disclosure; its analysis of every factor enumerated by
5 Congress in the Act weighed against such disclosures being sufficient. Thus, the 2017 study
6 strongly supports a conclusion by USDA that U.S. consumers will not have sufficient access to
7 GE food disclosure through electronic or digital disclosure alone.

8 *The Final Rule Deadline*

9 Despite USDA's knowing the July 29, 2018 hard deadline set by Congress to issue the
10 final rules, and multiple media reports that the proposed rules were imminent and planned to be
11 released for public comment by the end of 2017, USDA in fact did not issue the draft rules by the
12 end of 2017, for unknown reasons. Instead, USDA did not issue the proposed draft rules until
13 many months later, on May 4, 2018. National Bioengineered Food Disclosure Standard, 83 Fed.
14 Reg. 19860 (May 4, 2018).

15 USDA's May 4 proposed rule finally set forth some proposed metrics for the rule for
16 comment, but in other instances made several proposals instead of just one it was endorsing, or
17 continued to leave other major questions unanswered with a definitive proposal. For example, as
18 to a *de minimis* threshold of GE content, USDA set forth three options rather than one proposal.
19 For on-package labeling, the agency gave multiple potential symbols. For the scope of the
20 classification, the agency gave two vastly different options as to whether highly refined GE
21 foods, which are the vast majority of all GE foods, would be included or not. Nor did the
22 proposal make any recommendation whatsoever as to the efficacy of electronic or digital forms
23 of labeling and its own 2017 study's analysis and conclusions.

24
25 ²⁸ Deloitte, *Study of Electronic or Digital Link Disclosure A Third-Party Evaluation of*
26 *Challenges Impacting Access to Bioengineered Food Disclosure* (July 2017),
27 <https://www.ams.usda.gov/sites/default/files/media/USDA%20Deloitte%20Study%20of%20Electronic%20or%20Digital%20Disclosure%20170801.pdf>.

1 USDA opened a 60-day comment period on the proposal, with a deadline of July 3, 2018.
2 CFS submitted comments on the proposed rule. USDA failed to implement a national mandatory
3 GE food disclosure standard by the July 29, 2018 deadline.

4 *USDA's Repeated Acknowledgements of the Deadline*

5 USDA's failure to comply with the statute is not only contrary to law but also to the
6 Agency's interpretation of the law and public recognition of its mandatory duties. USDA has
7 repeatedly acknowledged its duty to comply with the statutory deadline. For example, a July 28,
8 2017 USDA website post states that:

9 The National Bioengineered Food Disclosure Standard Law was
10 enacted by Congress on July 29, 2016. AMS has two years to
11 establish the standard and the procedures necessary for
12 implementation. AMS is seeking input from stakeholders in order
13 *to establish the final rule by the mandated July 2018 deadline.*²⁹

14 In the May 3, 2018 announcement, USDA preemptively refused to permit any extension
15 to the 60-day comment period on its rule proposal, citing the mandatory statutory deadline:

16 The proposed rule is open for comment for 60 days. *Due to the*
17 *Congressionally mandated timeline for this rulemaking, the*
18 *comment period will not be extended*, so it is important that anyone
19 interested file comments in a timely manner.³⁰

20 Another example is a 2016 USDA Presidential Transition briefing document, received through
21 the Freedom of Information Act (FOIA), which lays out the intent and scope of the Act,
22 reiterating USDA's knowledge of the statutory deadline:

23 ²⁹ U.S. Dep't of Agric., *USDA Seeks Input in Developing a Proposed Bioengineered Food*
24 *Disclosure Rule* (June 28, 2017) [https://www.ams.usda.gov/content/usda-seeks-input-](https://www.ams.usda.gov/content/usda-seeks-input-developing-proposed-bioengineered-food-disclosure-rule)
25 [developing-proposed-bioengineered-food-disclosure-rule](https://www.ams.usda.gov/content/usda-seeks-input-developing-proposed-bioengineered-food-disclosure-rule) (last visited Sept. 5, 2018) (emphasis
26 added).

27 ³⁰ U.S. Dep't of Agric., *USDA Seeks Comments on Proposed Rule for National Bioengineered*
28 *Food Disclosure Standard* (May 3, 2018) [https://www.usda.gov/media/press-](https://www.usda.gov/media/press-releases/2018/05/03/usda-seeks-comments-proposed-rule-national-bioengineered-food)
29 [releases/2018/05/03/usda-seeks-comments-proposed-rule-national-bioengineered-food](https://www.usda.gov/media/press-releases/2018/05/03/usda-seeks-comments-proposed-rule-national-bioengineered-food) (last
30 visited Sept. 5, 2018) (emphasis added).

1 The legislation amends the Agricultural Marketing Act of 1946,
 2 *and requires that within two years of the Law's enactment USDA's*
 3 *Agricultural Marketing Service (AMS) establish a mandatory*
 4 *national bioengineered food disclosure standard and the*
 5 *procedures necessary to implement the national standard.*

6 Another USDA email, dated September 28, 2016, includes a quoted statement made by former
 7 United States Secretary of Agriculture, Tom Vilsack:

8 I think it's important for us to figure out a way to get this thing
 9 started so that we don't slip on the timeline that is important to
 10 meet in order for us *to meet the deadline set by Congress* to get
 11 (the final rule) in place within two years.

12 In further FOIA documents, the Agency acknowledged that failing to meet the mandatory
 13 deadline would be detrimental, as it would lead to "further confusion." Additional USDA
 14 documents repeatedly acknowledge the existence and importance of the mandatory 2018
 15 deadline.

16 Despite USDA's continuous recognition of its statutory obligations to finalize regulatory
 17 standards by the congressionally mandated deadline of July 29, 2018, USDA has not done so.

18 **STANDARD OF REVIEW**

19 Summary judgment is appropriate if no genuine issue of material fact exists and the
 20 moving party is entitled to judgment as a matter of law.³¹ Fed. R. Civ. P. 56(c); *Celotex Corp. v.*
 21 *Catrett*, 477 U.S. 317, 322-23 (1986). An issue is "material" if its resolution could affect the
 22 outcome of the action. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986).

23 The APA provides the basic framework for judicial review of agency action, inaction,
 24 and delays. 5 U.S.C. § 702. "Agency action" is defined to include "the whole or a part of any
 25 agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or *failure to act.*"
 26 *Id.* § 551(13) (emphasis added). Failure to act includes any "discrete agency action that it is

27
 28 ³¹ This motion is timely although filed prior to Defendants' answer. *See* Fed. R. Civ. P. 56
 advisory committee's note – 2010 Amendment (noting the rule "allows a motion for summary
 judgment to be filed at the commencement of an action[.]"); *see also Sec. Tr. Co. of Rochester,*
N.Y. v. Woodward, 73 F.Supp. 667, 671 (S.D.N.Y. 1947). (motion for summary judgment "may
 be made before answer, particularly where the only question involved is one of law.").

1 required to take,” including “when an agency is compelled by law to act within a certain time
 2 period.” *Norton v. S. Utah Wilderness Alliance*, 542 U.S. 55, 64-65 (2004). In such
 3 circumstances, “a reviewing court shall . . . hold unlawful and agency action, findings, and
 4 conclusions” found to be inter alia “arbitrary, capricious, an abuse of discretion, or otherwise not
 5 in accordance with law” or “without observance of procedure required by law.” 5 U.S.C. §
 6 706(2)(a), (d); *see also id.* § 555(b) (requiring agencies to act “within a reasonable time”).
 7 Finally, under the APA “a reviewing court *shall* compel agency action unlawfully withheld or
 8 unreasonably delayed.” 5 U.S.C. § 706(1) (emphasis added).

9 ARGUMENT

10 I. USDA’S FAILURE TO MEET CONGRESS’S EXPRESS GE LABELING ACT 11 DEADLINE ENTITLES PLAINTIFFS TO SUMMARY JUDGMENT.

12 The Ninth Circuit has emphatically stated that in instances where an agency misses an
 13 express Congressional deadline, the agency has *per se* violated the law; a court does not have
 14 discretion to balance the equities to determine whether a delay is reasonable. *See, e.g.*,
 15 *Biodiversity Legal Found.*, 309 F.3d at 1177-78 & n.11. Here, it is undisputed that USDA failed
 16 to comply with the GE Labeling Act regulation deadline—a deadline with which Congress
 17 expressly mandated that USDA “shall” comply.³² *See Bennett v. Spear*, 520 U.S. 154, 175
 18 (1997) (when statute “uses the imperative ‘shall,’” any contention that provision is “discretionary
 19 would fly in the face of its text”); *United States v. Monsanto*, 491 U.S. 600, 607 (1989) (by using
 20 “shall” in civil forfeiture statute, “Congress could not have chosen stronger words to express its
 21 intent that forfeiture be mandatory in cases where the statute applied”); *Pierce v. Underwood*,
 22 487 U.S. 552, 569-70 (1988) (Congress’s use of “shall” in a housing subsidy statute constitutes
 23 “mandatory language”). Therefore, the Court should grant Plaintiffs’ motion for summary

24 ³² GE Labeling Act § 293(a), 130 Stat. at 835 (codified at 7 U.S.C. § 1639b(a)) (“Not later than 2
 25 years after July 29, 2016, the Secretary *shall* – (1) establish a national mandatory bioengineered
 26 food disclosure standard with respect to any bioengineered food and any food that may be
 27 bioengineered; and (2) establish such requirements and procedures as the Secretary determines
 28 necessary to carry out the standard.”) (emphasis added).

1 judgment and grant the relief requested.

2 In *Biodiversity Legal Foundation*, environmental groups sued the U.S. Fish and Wildlife
3 Service (Service) for its failure to comply with deadlines imposed by the Endangered Species
4 Act (ESA) for making findings as to whether numerous species warranted listing as endangered
5 or threatened. 309 F.3d at 1169-70. Like the Act's deadlines, the ESA imposed a mandatory
6 twelve-month deadline for making listing determinations, which the Service failed to meet. *Id.* at
7 1171. The district court relied on *Forest Guardians v. Babbitt*, 174 F.3d 1178, 1179 (10th Cir.
8 1999), holding that: 1) when an agency fails to comply with a statutorily-imposed deadline, it has
9 unlawfully withheld action; and in such cases 2) the APA requires a court to issue relief.
10 *Biodiversity Legal Found.*, 309 F.3d at 1176 (citing *Forest Guardians*, 174 F. 3d at 1191). The
11 district court therefore granted partial summary judgment in plaintiffs' favor and issued an
12 injunction requiring the Service to make the requested final listing determinations. *Id.* at 1176.

13 On appeal, the Ninth Circuit affirmed, holding that "Congress imposed a twelve-month
14 deadline for final determinations under the ESA" and that the agency's "failure to comply with
15 the twelve-month deadline is not in accordance with the ESA, the governing law." *Id.* at 1177. In
16 so doing, the Ninth Circuit rejected the Service's argument that the court has discretion to
17 balance the equities:

18 The Service urges us to apply the TRAC factors developed in
19 *Telecommunications Research & Action Ctr. v. FCC*, 750 F.2d 70, 80 (D.C. Cir.
20 1984), and considered by us in *Brower v. Evans*, 257 F.3d 1058, 1068 (9th Cir.
21 2001). However, in *Brower*, we were considering whether there was an
22 unreasonable delay in the absence of a firm deadline. *Id.* In this case, Congress
has specifically provided a deadline for performance by the Service, *so no*
balancing of factors is required or permitted.

23 *Id.* at 1177 n.11 (emphasis added); *accord id.* at 1178 (holding that "[t]he exercise of discretion
24 is foreclosed when statutorily imposed deadlines are not met").

25 This court recently relied on *Biodiversity Legal Foundation* in holding the Food and Drug
26 Administration (FDA) unlawfully withheld the promulgation of multiple food safety regulations

27

28

1 that Congress mandated in the Food Safety Modernization Act. *See Ctr. for Food Safety v.*
2 *Hamburg*, 954 F.Supp. 2d 965 (N.D. Cal. 2013). The court explained that declaratory relief was
3 proper since FDA “admittedly failed to comply with the mandatory rulemaking schedule” and
4 that “no balancing of [the *TRAC*] factors is required or permitted . . . where Congress has
5 specifically provided a deadline for performance by an agency[.]” *Id.* at 970-71 (quoting
6 *Biodiversity Legal Foundation*).

7 In addition to *Hamburg*, this court has relied on *Biodiversity Legal Foundation* and
8 *Forest Guardians* in repeatedly holding that, where an agency fails to meet a mandatory
9 Congressional deadline, that is the end of the court’s inquiry: the agency has *per se* violated the
10 law, and no *TRAC* balancing is appropriate. *See, e.g., Natural Res. Defense Council v. Evans*,
11 243 F. Supp. 2d 1046, 1057 (N.D. Cal. 2003) (“The Ninth Circuit has explicitly held the *TRAC*
12 factors to be inapplicable where Congress has set a specific deadline for agency action.”) (citing
13 *Biodiversity Legal Foundation*); *id.* at 1057 (“Since the Magnuson-Stevens Act sets specific,
14 mandatory deadlines for agency action on rebuilding plans and bycatch, [the agency’s] lengthy
15 timing arguments based on the *TRAC* factors are invalid under this binding precedent.”); *Ctr. for*
16 *Biological Diversity v. Abraham*, 218 F. Supp. 2d 1143, 1148 (N.D. Cal. 2002) (Department of
17 Energy violated the law by failing to comply with the mandatory deadlines set in the Energy
18 Policy Act); *id.* at 1159-60 (Rejecting *TRAC* because the “Ninth Circuit has recently spoken to
19 this very issue” and citing both *Biodiversity Legal Foundation* and *Forest Guardians*); *id.* at
20 1164 (holding the same, in the specific context of rules that failed to meet a Congressional
21 timetable, again citing both *Biodiversity Legal Foundation* and *Forest Guardians*); *Ctr. for*
22 *Biological Diversity v. Brennan*, 571 F. Supp. 2d 1105, 1131-1132 (N.D. Cal. 2007) (granting
23 plaintiffs summary judgment, holding the defendant agency had unlawfully withheld research
24 plans required by the Global Change Research Act and rejecting defendant’s arguments that it
25 had discretion beyond the statutory deadlines) (citing *Forest Guardians*); *id.* at 1132 (showing no
26 deference to the agency because Congress has imposed “clear-cut, unambiguous deadlines for
27 compliance”); *Razaq v. Poulos*, No. C 06-2461 WDB, 2007 WL 61884, at *6 (N.D. Cal. 2007)

28

1 (holding *TRAC* factors appropriate “[w]here the governing statute specifies no deadline for a
 2 governmental act”) (citing *Biodiversity Legal Found.*). Accordingly, *TRAC* balancing is only
 3 appropriate in the absence of an express Congressional deadline.³³

4 In sum, USDA failed to meet the GE Labeling Act’s express deadline for its regulations.
 5 This requires entrance of summary judgment in Plaintiffs’ favor. All that remains for the court to
 6 consider is the nature of the further relief best suited for the agency’s violation of law.

7 **II. USDA’S VIOLATIONS OF THE GE LABELING ACT AND THE APA REQUIRE**
 8 **EQUITABLE AND INJUNCTIVE RELIEF.**

9 This Court should grant summary judgment in favor of Plaintiffs as a matter of law,
 10 because USDA failed to comply with Congress’s mandated GE Labeling Act deadline—and
 11 issue injunctive relief compelling USDA to act. In such instances, the APA requires that “[t]he
 12 reviewing court *shall* . . . compel agency action unlawfully withheld or unreasonably delayed.” 5
 13 U.S.C. § 706(1) (emphasis added). Further, it is the law in this Circuit that when an agency has
 14 failed to comply with a statutorily-imposed deadline, a court must issue injunctive relief and
 15 compel agency action. *Biodiversity Legal Found.*, 309 F.3d at 1177-78 (upholding the district
 16 court’s denial of defendants’ request for additional time, finding that the court’s discretion in
 17 fashioning injunctive relief “is foreclosed when statutorily imposed deadlines are not met”); *see*
 18 *also Forest Guardians*, 174 F.3d at 1190 (“The agency must act by the deadline. If it withholds
 19 such timely action, a reviewing court *must* compel the action unlawfully withheld.”) (emphasis
 20 added).

21 In *Center for Food Safety v. Hamburg*, this Court held that when Congress set deadlines
 22 in the Food Safety Modernization Act, it “signaled its intention that the process be closed-ended,

23
 24 ³³ Express statutory deadlines like those in the GE Labeling Act are exceedingly rare,
 25 underscoring their importance as well as why this case is different than the vast majority of cases
 26 challenging agency delay. *See* Jacob E. Gersen & Anne Joseph O’Connell, *Deadlines in*
 27 *Administrative Law*, 156 U. Pa. L. Rev 923, 941 & 983 tbl.4 (2008) (scholars’ comprehensive
 28 review of agency rulemaking actions between 1988 and 2003 found that only approximately
 eight percent of all agency actions were associated with a statutory deadline).

1 rather than open-ended,” and discretion regarding the *substance* of regulations does not translate
2 to discretion to decide *when* to finalize regulations, and accordingly, the imposition of deadlines
3 through injunctive relief was consistent with Congress’s purposes in setting statutory deadlines
4 for food safety regulations. 954 F. Supp. 2d at 971-72.

5 Thus, the Court should: 1) declare that USDA has not complied with the deadline
6 Congress set in the GE Labeling Act; and 2) compel USDA to promulgate and finalize the
7 required GE food disclosure standard by a date certain. *See, e.g., Biodiversity Legal Found.*, 309
8 F.3d at 1176-78 (affirming the district court’s issuance of declaratory and injunctive relief
9 compelling defendant agency to make the requested final determinations); *Hells Canyon Pres.*
10 *Council v. Richmond*, 841 F. Supp. 1039, 1048-50 (D. Or. 1993) (declaring that defendant Forest
11 Service unreasonably delayed action and compelling agency to act by proposed schedule).

12 Plaintiffs respectfully request that the Court order the Defendants to issue the mandated
13 GE Labeling Act standard within 60 days. The Court may determine the appropriate schedule for
14 the completion of the unlawfully withheld standard in numerous ways. *Earth Island Inst. v.*
15 *Carlton*, 626 F.3d 462, 475 (9th Cir. 2010) (“To be sure, district courts have ‘broad latitude in
16 fashioning equitable relief when necessary to remedy an established wrong.’”) (quoting *Sierra*
17 *Hikers Ass’n v. Blackwell*, 390 F.3d 630, 641 (9th Cir. 2004)).³⁴ For example, the Court could
18 order the parties to stipulate to deadlines for USDA to finalize the standard, *see e.g., Ctr. for*
19 *Food Safety v. Hamburg*, 954 F. Supp. 2d at 972 (ordering Plaintiffs and FDA to meet and confer
20 and jointly propose deadlines); or the Court could require USDA to supply the Court with
21 expedited dates, and afford Plaintiffs an opportunity to oppose Defendant’s proposed deadline.
22 *See, e.g., Biodiversity Legal Found. v. Badgley*, No. 98-1093-KI, 1999 U.S. Dist. LEXIS 17806,
23 at *20-21 (D. Or. Nov. 17, 1999) (adopting an expedited schedule to complete delayed agency

24 _____
25 ³⁴ However, in issuing a remedy, a court’s only choice “is simply whether a particular means of
26 enforcing the statute should be chosen over another permissible means, . . . not whether
27 enforcement is preferable to no enforcement. . . .” *United States v. Oakland Cannabis Buyers’*
28 *Co-op.*, 532 U.S. 483, 497–98 (2001).

1 action that the defendant had proposed and to which plaintiffs agreed); *Natural Res. Defense*
2 *Council v. Evans*, 290 F. Supp. 2d. 1051, 1051-52, 1056 (N.D. Cal. 2003) (granting plaintiffs’
3 motion for an order for deadlines after the parties were unable to stipulate to a new schedule by
4 which the defendant National Marine Fisheries Service must comply with statutory deadlines);
5 *Hells Canyon Pres. Council*, 841 F. Supp. at 1048-50 (adopting the parties’ proposed schedule).

6 Plaintiffs further request that, in light of USDA’s unlawful withholding of the mandatory
7 GE food disclosure standard beyond the statutorily-mandated deadline, the Court should retain
8 jurisdiction to ensure agency compliance with the Court-mandated schedule for completion of
9 the standard. *See Thomas*, 658 F. Supp. at 175 (stating that the court will retain jurisdiction and
10 the power to hold defendant EPA in civil contempt and issue appropriate sanctions in the event
11 of noncompliance, in light of EPA’s repeated delays).

12 **CONCLUSION**

13 For the foregoing reasons, Plaintiffs are entitled to summary judgment in this case, and
14 the Court should compel Defendants’ unlawfully withheld actions.

15
16 Respectfully submitted this 6th day of September 2018 in Portland, Oregon.

17 /s/ George Kimbrell
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CERTIFICATE OF SERVICE

I, George Kimbrell, certify that on September 6, 2018, I served true and correct copies of the foregoing Motion for Summary Judgment and Memorandum of Points and Authorities, by electronically filing the foregoing with the Clerk of the Court for the United States District Court for the Northern District of California, via CM/ECF. I further certify that as to participants in the case who are not registered CM/ECF users, I served the foregoing document by depositing it in the U.S. Mail, addressed as follows:

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/s/ George Kimbrell
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