

Dear Secretary Vilsack,

Thank you for your years of public service and dedication to securing a healthy, prosperous, and sustainable agricultural sector. Respectfully, we wish to point out that USDA policies on genetically modified organisms (GMOs) work in opposition to these goals and are undermining your efforts.

Regulations on GMOs, including gene editing, are based on unscientific and often disproved assumptions. We urge you to update USDA's current policies, as well as the APHIS Five Year Strategic Plan, to better incorporate state-of-the-art science. We offer evidence below that demonstrates how current false suppositions put our health, environment, and food supply at grave risk.

USDA ignores dangerous, unpredictable side effects of gene editing

USDA policy is based on the incorrect assertion that gene editing techniques such as CRISPR are safe, precise, predictable, and even natural. As a result, USDA does not regulate most gene edited organisms.

In fact, the side effects of gene editing are so significant, the journal *Nature* summarized the results of three CRISPR experiments as "Chromosomal Mayhem." Gene editing not only fails to overcome most of the unpredictable outcomes associated with earlier forms of genetic engineering, some experts assert that it is worse. Jonathan Latham, Ph.D., editor of *Independent Science News* and former genetic engineer states, "The evidence so far is that gene editing does even more damage to genomes and is even more unpredictable than standard genetic engineering."

Please view this [six-minute animated video](#) that reveals what actually occurs inside gene edited plants, all based on peer-reviewed studies. The illustrations make it easier to appreciate the extent of the damage.

The various mutations, additions, deletions, and epigenetic changes lie outside the type and frequency associated with natural breeding. Unpredictable changes regularly produced by gene editing, according to molecular geneticist Michael Antoniou, Ph.D., "could result in increased production of toxins and allergens." The altered patterns of gene function and biochemistry can also result in unpredictable agronomic and environmental impacts.

Tragically, most developers who use the technology fail to conduct the follow-up testing needed to identify the range of surprise side effects. Therefore, potentially dangerous gene edited products could easily be introduced into the food supply and environment.

Below is a summary of seven ways that gene editing is dangerous and unpredictable. Biotech advocates have yet to reliably address *any* of them.

To put these adverse impacts in context, it is helpful to understand that the gene editing tool CRISPR uses a molecular scissors that cuts the genome, and a guide that tells the scissors where to cut. The one doing the experiment hopes that when the genome is repaired and rejoined by the cell, the newly constructed sequence will match their intentions.

1. Off Target Effects

Gene editing often cuts the genome and creates mutations in unintended "off-target" areas.

2. Mutations During Genome Repair

The mechanisms used by cells to repair and rejoin the broken ends of the DNA strands can result in DNA insertions, deletions, and rearrangements.

3. Foreign Genes Accidentally Inserted

During genome repair, random pieces of DNA floating in the petri dish can become integrated. The most famous example was the gene edited hornless cows that ended up with antibiotic-resistant bacterial DNA inserted into their genomes.

4. Mutant Proteins

Gene editing can knockout or silence genes. Researchers at Penn State, for example, used CRISPR to knockout the gene that causes mushrooms to turn brown when sliced. In 2016, USDA wrote a letter to the developers, confirming that the Department does not regulate or require assessments, and the mushrooms could be cultivated and sold without government oversight. Three years later, however, an article in [Nature Methods](#) revealed that CRISPR knockouts failed about 1/3 of the time. In some cases, the partially disabled gene encodes mutant proteins that could be allergenic or toxic. There's no indication that the Penn State mushroom was ever tested for the presence of these dangerous proteins.

5. Insertion damage

The process of inserting the gene editing machinery into the cell can cause unpredictable mutations.

6. Cloning Mutations

The process used to grow plant cells in laboratories before gene editing, and the process of cloning cells afterwards, typically result in hundreds or thousands of mutations.

7. Epigenetic inheritance

In addition to altering sequences within the genome, gene editing can cause epigenetic changes that alter how much protein genes produce. Such changes can be inherited. For example, gene edited mice passed down epigenetic changes to at least 10 generations.

These seven impacts are illustrated in the short animation, and are part of the indisputable evidence that the disruptions caused by gene editing are different than natural breeding. Strict regulations and assessments are necessary to protect our health, our environment, and our food supply.

By not requiring gene edited foods to be labeled, USDA puts our health at risk

As you are aware, more than half of US consumers believe that genetically modified foods carry long term health risks. According to research over the last 20 years, they are correct.

In the case of allergens, for example, after genetically modified Bt corn was on the market, independent scientists discovered that it produces a new allergen, gamma zein, not found in natural corn.

Similarly, Roundup Ready corn was in our food supply for years before researchers found that it produces higher levels of putrescine and cadaverine, which are linked to allergic reactions (as well as cancer.)

A May 2023 study, published more than 25 years after Roundup Ready soy was being consumed by Americans, reported that “the allergenicity analysis identified 43 proteins with allergenic potential being differentially expressed in the GM soybean variety.”

These are but a few examples of ways in which GMOs might be increasing allergic reactions.

Are they? Allergists, as well as those with allergies, have repeatedly told IRT that GMOs do lead to unique or more severe allergic reactions. We have seen multiple case studies, large survey results, and a consistent increase in allergic reactions in the US populations paralleling the consumption of GMOs.

But there is no government or public health surveillance system, and no adequate labeling laws, to confirm a health impact. Instead, we hear the relentless, unscientific claim of biotech advocates that no one has suffered a health issue because of eating GMOs. In truth, it is a dangerous application of, “Don’t ask. Don’t tell.”

The process of gene editing can, *without a doubt*, introduce new allergens or toxins, or elevate existing allergens and toxins. Since there are no comprehensive safety assessments, many of these dangerous changes will, *without a doubt*, be overlooked by developers. (We have already confirmed this issue with GMOs created by earlier methods.)

By not requiring gene edited foods to be labeled, USDA is, *without a doubt*, increasing the risk of allergic and other reactions in the population.

Consider the person who gets an allergic reaction after eating a meal that contains an unlabeled gene edited ingredient. How would they begin to track the cause. This becomes even more difficult when the same person later eats the natural version of that food but doesn’t get a reaction. They might never identify the cause, but could spend the rest of their life reacting or not reacting without knowing why.

Now multiply this occurrence to include dozens, perhaps hundreds or thousands of new gene edited foods quietly slipped into our diet. Such an influx is now facilitated by the low cost and accessibility of gene editing, combined with USDA’s abdication of regulations. As the number of gene edited foods grows, the chances that some will cause allergic reactions in at least some members of the public quickly approaches 100%. Allergic reactions can be severe, even deadly.

Labeling of gene edited foods is a medical and ethical necessity. We urge you to require labels on gene edited ingredients, and eliminate all loopholes in the current labeling system. Otherwise, USDA makes it difficult or impossible for people to choose their food, track possible reactions, and prevent future exposure. This is a life-or-death issue.

Secretary Vilsack, you have repeatedly offered to sit down and discuss issues with people who have a variety of viewpoints. We wish to take you up on your offer and assemble a group of expert scientists who can demonstrate that the risks described here are valid. In truth, the list of references included with this letter should already be sufficient to compel an immediate change in USDA policy on GMOs, including those created by gene editing.

Sincerely,

Jeffrey Smith, the team at IRT, and supporters