



March 15, 2024

Comments submitted to the USMCA Secretariat by Center for Food Safety  
Transmitted via email to: [ssmtlc@economia.gob.mx](mailto:ssmtlc@economia.gob.mx)

Dear Secretariat,

Center for Food Safety appreciates the opportunity to provide comments on the Mexican government's decree restricting imports of genetically engineered white corn and phaseout of glyphosate.

## Introduction

Center for Food Safety (CFS) is the leading public interest voice on genetically engineered crops and foods, also known as GMOs, in the U.S. Our legal and science staff have unmatched expertise in this arena. CFS has sued government agencies over their "regulation" of GMOs and associated pesticides, and prevailed several times. In one case, a U.S. federal court took the unprecedented step of striking down the U.S. Environmental Protection Agency's (EPA's) human health assessment of a pesticide, glyphosate, as discussed further below.

In these comments, we first explain why, contrary to popular belief, GMOs are not truly regulated in the U.S., as the term is defined under the United States-Mexico-Canada Agreement (USMCA), which casts grave doubt on U.S. protestations regarding GMO safety. Then we discuss several episodes in which yellow and white maize products have been contaminated with potentially hazardous GMOs. Finally, we explain the some of the health hazards (e.g. cancer) posed by glyphosate that the U.S. government refuses to acknowledge.

## The U.S. Government Does Not Ensure the Safety of GMOs

The U.S. government has worked hard to promote its agricultural biotechnology industry. The U.S. "regulatory" system for GMOs is a critical element of these promotional efforts. It is largely a sham enterprise whose purpose is to persuade the public (U.S. and international) that GMOs have been evaluated and found to be safe, rather than to actually protect public health and the environment. Evidence for this includes the extraordinary influence the Monsanto Company, premier developer of GMOs, exerted on the U.S. government in shaping the U.S. regulatory regime;<sup>1</sup> the numerous GE crop contamination episodes that have occurred due to government's failure to impose adequate gene containment measures;<sup>2</sup> and the voluntary nature of and deficiencies in U.S. GMO regulation.<sup>3</sup>

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<sup>1</sup> Eichenwald K et al. (2001). Biotechnology Food: From the Lab to a Debacle. The New York Times, January 25, 2001, <https://tinyurl.com/38ma8fau>.

<sup>2</sup> U.S. Government Accountability Office (2008). Genetically Engineered Crops: Agencies are proposing changes to improve oversight, but could take additional steps to enhance coordination and monitoring, GAO-09-60, Nov. 2008, see App. VII, pp. 90-95. <https://www.gao.gov/assets/gao-09-60.pdf>.

<sup>3</sup> Freese W and Schubert D (2004). Safety Testing and Regulation of Genetically Engineered Foods. Biotechnology and Genetic Engineering Reviews 21(1): 299-324. <https://tinyurl.com/4yf7am7e>.

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The agencies that supposedly oversee GMOs are the U.S. Food and Drug Administration, the U.S. Department of Agriculture, and the U.S. Environmental Protection Agency.

### The U.S. Food and Drug Administration (FDA) Does Not Regulate GMOs

The agency most often cited for regulation of GMOs in the U.S. is the FDA. Yet what passes for regulation is so deficient that it fails in two respects to meet the definition of “regulation” under USMCA:

“**regulation** means a *measure of general application* adopted, issued, or maintained by a regulatory authority *with which compliance is mandatory*.”<sup>4</sup>

#### *Voluntary, secretive and superficial*

FDA does not require a GE plant developer to do anything prior to marketing its GE crop or food derived from it. Instead, FDA operates what it calls a voluntary consultation program that is designed to enhance consumer confidence and speed GE crops to market.<sup>5</sup> This program is not based on a statute, but rather on a “guidance document.”<sup>6</sup> Consultations are conducted in secret, and involve only FDA and industry. The developer may provide FDA with a summary of whatever data it has developed to support a conclusion that the GE plant is substantially equivalent to conventional varieties, and thus “generally recognized as safe.”<sup>7</sup> Yet the FDA “does not conduct a comprehensive scientific review of data generated by the developer,”<sup>8</sup> and thus cannot identify intentional or unintentional errors or misrepresentations. The company is under no legal obligation to consult with FDA at all, or to provide it with any specific data. Thus, the FDA consultation program is not mandatory, but rather entirely voluntary, and hence does not constitute regulation as defined under the USMCA.

#### *No “measures of general application”*

Not only is FDA’s consultation program optional rather than mandatory, it also fails to specify “measures of general application” with which GE plant developers could comply – a second breach of “regulation” as defined under USMCA. Companies that choose to consult with FDA share summaries of whatever data they may have developed, most commonly targeted analyses of the levels of a handful of major GE plant components and nutrients. But FDA does not specify which plant components need be measured for particular crops, what constitutes acceptable or unacceptable deviations from the conventional norm, nor testing methods. Moreover, FDA has failed to update its guidance to industry, which is based on a 1992 policy statement, to account for improved testing techniques. Thus, FDA does not even recommend that companies conduct metabolomic or proteomic analyses of the sort long advocated by scientists to detect potentially hazardous unintended effects of the genetic

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<sup>4</sup> USMCA, Article 28.1: Definitions (italics added).

<sup>5</sup> FDA’s Voluntary Plant Biotechnology Consultation Program Eases Pathway to Marketplace, FDA, March 21, 2019, <https://tinyurl.com/yvh8j8jr>.

<sup>6</sup> FDA, Guidance for Industry: Consultation Procedures under FDA’s 1992 Statement of Policy for Foods Derived from New Plant Varieties, <https://tinyurl.com/24e62849>, last visited 3/15/24.

<sup>7</sup> FDA, Statement of Policy: Foods Derived from New Plant Varieties, Federal Register Vol. 57, No. 104: 22984-22992 (May 29, 1992).

<sup>8</sup> See ft. 6.

engineering process.<sup>9</sup> For example, Roundup Ready maize variety NK603 sailed through FDA consultation as “substantially equivalent” based on summary data from Monsanto.<sup>10</sup> But a comprehensive “-omics” analysis of NK603 found it to be substantially different than an isogenic conventional comparator, with altered levels of enzymes and metabolites indicative of an imbalance in energy metabolism and oxidative stress.<sup>11</sup> Neither does FDA recommend animal feeding studies with GE crops, and such animal studies are rarely conducted by companies as part of the FDA consultation process.

### *Deficits in FDA consultations*

As a result of these weaknesses, when companies do choose to consult, the data they submit to FDA is quite inconsistent, varying sharply from crop to crop.<sup>12</sup> GE crop developers sometimes refuse to comply with FDA requests for additional data, without repercussions. FDA also misses obvious errors in industry data submissions. Developers sometimes fail to provide (adequate) data on levels of important native toxins, anti-nutrients, and allergens; bias their allergenicity testing to achieve negative results; and provide insufficient detail to enable determination of whether the GE crop is safe or not.

In one instance, FDA wrongly assumed that the most widely planted insect-resistant corn variety (MON810) contained a complete copy of the *cry1Ab* gene expressing an insecticidal toxin. In fact, the genetic engineering process had gone awry, the *cry1Ab* genetic construct had broken apart during transformation, and only a fragment of the gene was incorporated in MON810, potentially resulting in expression of a fusion protein.<sup>13</sup> It is not clear whether MON810 developer Monsanto lied to FDA, or the FDA reviewer bungled the consultation. In either case, this fundamental error illustrates the *pro forma*, rubber-stamp nature of FDA “regulation.”

### *The GE plant developer, not FDA, bears responsibility for the safety of the GE plant*

Contrary to popular belief, FDA does **not** approve GE crops as safe for human or animal consumption. Instead, at the end of the consultation, FDA merely issues a memo summarizing the GE crop developer’s findings and a letter that conveys the company’s view that the GE crop is substantially equivalent to conventional varieties.<sup>14</sup>

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<sup>9</sup> Kuiper HA et al. (2001). Assessment of the food safety issues related to genetically modified foods. *The Plant Journal* 27(6): 503-528.

<sup>10</sup> FDA, Biotechnology Consultation Note to the File BNF No. 000071 for Monsanto Roundup Ready Corn line NK603, October 9, 2000. <https://shorturl.at/oqFI9>.

<sup>11</sup> Mesnage R et al. (2016). An integrated multi-omics analysis of the NK603 Roundup-tolerant GM maize reveals metabolism disturbances caused by the transformation process. *Nature Scientific Reports* 6:37855. <https://www.nature.com/articles/srep37855>.

<sup>12</sup> For the following discussion, see: Doug Gurian-Sherman, Ph.D. Holes in the Biotech Safety Net, Center for Science in the Public Interest, 2003. <https://tinyurl.com/5cvtzy3e>. The report is based on Dr. Gurian-Sherman’s critical assessment of 14 data submissions to FDA by GE plant developers and related communications.

<sup>13</sup> Freese and Schubert (2004), op. cit., p. 311.

<sup>14</sup> A typical example is EPA’s letter to Monsanto regarding its widely planted Bt corn, event MON810: “Based on the safety and nutritional assessment you have conducted, it is our understanding that Monsanto has concluded that corn products derived from this new variety are not materially different in composition, safety, and other relevant parameters from corn currently on the market, and that the genetically modified corn does not raise issues that would require premarket review or approval by FDA. .... as you are aware, it is Monsanto’s

## The U.S. Department of Agriculture (USDA) Exempts GMOs from Regulation

The USDA once regulated GMOs under the Plant Pest Act, a 1957 statute intended to prevent the introduction and spread of plant pathogens, insect pests and parasitic plants.<sup>15</sup> GE plant developers would easily obtain permits from USDA to grow GMOs in field trials with gene containment measures. Companies wishing to commercialize a GMO would petition USDA for “nonregulated status.” Once granted by USDA, companies could grow the GMO without any regulation or segregation from non-GE crop varieties. USDA has never to our knowledge rejected a petition for commercialization of a GMO.

USDA overhauled its biotechnology regulations in 2020 to provide “regulatory relief” to GE plant developers.<sup>16</sup> Under the SECURE Rule, USDA exempts large classes of GMOs from any oversight at all, even at the field trial stage of development.<sup>17</sup> In less than three years, USDA has confirmed exemptions for 79 GE plants, including three GE maize varieties.<sup>18</sup> This is likely the tip of the iceberg, since USDA allows companies to “self-determine” whether or not their GE crops are regulated, without consulting USDA at all.<sup>19</sup> As a result, a huge variety of different GE plants with a broad range of traits can be grown without gene containment measures, without safety assessment, and without even informing USDA that the GE crops are being grown. This deregulatory regime will result in far more GE crop contamination episodes, especially with wind-pollinated maize.

Like the FDA, USDA does not regulate GMOs as defined under Article 28.1 of USMCA. Because the SECURE Rule has so many exemptions, USDA’s regulatory regime does not have “measures of general application” to all GMOs. Because USDA empowers companies to “self-determine” whether their GE crops are even to be regulated at all, there is no mandatory compliance.

## The U.S. Environmental Protection Agency (EPA) Mis-Regulates Potentially Hazardous Bt Maize

The EPA ostensibly regulates GE crops like maize that contain insecticidal toxins that may pose hazards to people. However, as detailed below, its oversight is deficient in numerous respects.

## **Potentially Hazardous GE Maize Contaminates Food Supply, Including White Maize**

### Bt Corn and Food Allergies

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responsibility to ensure that foods marketed by the firm are safe, wholesome and in compliance with all applicable legal and regulatory requirements.” See: <https://tinyurl.com/ybm66bww>.

<sup>15</sup> For following discussion, see Freese and Schubert (2004), op. cit., pp. 301-302.

<sup>16</sup> U.S. Dept. of Agriculture, SECURE Rule: Questions & Answers, June 2020.

<https://www.aphis.usda.gov/biotechnology/340-secure-rule-qa.pdf>.

<sup>17</sup> CFS (2024). Comments on Movement of Organisms Modified or Produced Through Genetic Engineering: Notice of Proposed Exemptions, Center for Food Safety, January 19, 2024.

<https://www.regulations.gov/comment/APHIS-2023-0022-6460>.

<sup>18</sup> See <https://tinyurl.com/473tv9eu>, last visited 3/14/24. Exempted GE maize varieties have alterations in yield, reproduction, and seed nutrient availability.

<sup>19</sup> CFS (2021). Conservationists and farmers sue over Trump Administration removal of most genetically engineered organism regulation. Center for Food Safety, July 26, 2021. <https://tinyurl.com/5583x5pw>.

Like FDA, EPA oversight lacks “measures of general application” that must be complied with – the hallmark of regulation under USMCA – for the pesticide-promoting GE plants under its jurisdiction. This is best exemplified by the Agency’s hapless attempts to address the potential for GE corn to cause food allergies. Food allergies afflict 32 million U.S. Americans, including 1 in 13 children, and have increased by 50% since the 1990s.<sup>20</sup> The potential for novel or upregulated proteins in GMOs to cause food allergies is a long-standing concern, driving development of assessment protocols.<sup>21</sup> Allergic reactions can be mild, but they can also cause life-threatening anaphylactic shock, which is far more likely to be fatal in children than adults.<sup>22</sup> Conventional corn is regarded as one of the safest grains for allergy-prone individuals, and often comprises a large part of food-allergic infants’ diets.<sup>23</sup> Today, however, 85% of corn in the U.S. has been rendered potentially allergenic because it is genetically engineered to express one or more crystalline insecticidal endotoxins (denoted Cry) derived from the soil bacterium, *Bacillus thuringiensis* – so-called Bt corn.<sup>24</sup>

In 1998, EPA approved a Bt corn variety known as StarLink, but only for consumption by livestock.<sup>25</sup> Human food use was prohibited because leading food allergists told EPA that StarLink’s endotoxin, Cry9C, had allergenic properties. Restrictions intended to prevent StarLink from contaminating the human food supply (e.g. buffer zones) failed miserably, and in the year 2000 Friends of the Earth conducted testing that found StarLink had massively contaminated corn products, resulting in recalls of tortillas, taco shells, corn flour and other corn products from supermarket shelves. Even though StarLink had only been bred into yellow dent corn varieties, cross-pollination and commingling resulted in the contamination of white corn products as well.<sup>26</sup>

Subsequent government investigations revealed that some consumers of corn products suffered severe allergic reactions that were potentially caused by Cry9C contamination. While the question of Cry9C’s allergenicity was never settled with certainty, an EPA Scientific Advisory Panel that exhaustively reviewed the StarLink affair was concerned enough to advise EPA that it *could not identify a safe level of Cry9C in the food supply*, leading EPA to reject a request to sanction low-level contamination.<sup>27</sup> Although further planting of StarLink was banned, efforts to remove it from the food supply had to be continued for several years.

Although EPA did not identify allergenicity concerns for Bt corn expressing different endotoxins, many credible studies do. In fact, the Cry1Ab endotoxin expressed in the most widely planted Bt corn varieties exhibits three properties of food allergens: resistance to digestion in simulated gastric fluid, heat stability (similar to StarLink’s Cry9C in both respects), as well as amino acid homology to a known allergen (vitellogenin), as shown in a study by FDA

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<sup>20</sup> M. Glim. Digging up the roots of food allergies, Intramural Research Program, U.S. National Institutes of Health, May 17, 2023. <https://tinyurl.com/5n7pm2vk>.

<sup>21</sup> Metcalfe DD (2003). Introduction: What are the issues in addressing the allergenic potential of genetically modified foods? *Environmental Health Perspectives* 111(8): 1110-1113.

<sup>22</sup> Cianferoni A and Muraro A (2012). Food-Induced Anaphylaxis. *Immunol Allergy Clin North Am.* 32(1): 165-195.

<sup>23</sup> Freese B (2001). The StarLink Affair, Friends of the Earth, 2001, pp. 25-26. <https://tinyurl.com/34cu9x2v>.

<sup>24</sup> USDA, Adoption of Genetically Engineered Crops in the U.S., <https://tinyurl.com/mrkv88y7>.

<sup>25</sup> For following discussion, see Bucchini L and Goldman LR (2002). StarLink Corn: A Risk Analysis. *Environmental Health Perspectives* 110(1): 5-13. <https://tinyurl.com/4z75msfx>.

<sup>26</sup> Kaufman M, Engineered corn found in white tortilla chips. *The Washington Post*, July 4, 2001. <https://tinyurl.com/33pzzd5f>.

<sup>27</sup> Bucchini L and Goldman LR (2002), op. cit.

scientist Steven Gendel.<sup>28</sup> Although presented with this information,<sup>29</sup> EPA failed to act, in sharp contrast to its response to StarLink contamination.

EPA has never established standardized allergenicity test protocols – “measures of general application” – for novel GE insecticidal proteins, but rather continues to rely on industry tests biased to achieve negative results. If conducted according to standardized protocols established by a prestigious international committee of the World Health and Food and Agriculture Organizations in 2001,<sup>30</sup> testing of these newer Bt endotoxins would undoubtedly also raise red flags for allergenicity.

Since approving Cry1Ab, the endotoxin in the first Bt corn varieties, EPA has gone on to approve many new GE corn varieties, each with up to six different Bt endotoxins.<sup>31</sup> The Agency has exempted each Cry toxin from the requirement of a tolerance – meaning there is no maximum residue level (MRL) for any single endotoxin in any Bt crop.<sup>32</sup> Nor is there any limit to the cumulative level of all Cry endotoxins combined.<sup>33</sup>

Without post-market surveillance, and without GMO food labeling for most processed foods, it is extremely difficult to identify the source of allergic reactions that may in fact be occurring to Bt endotoxins in the American food supply. With 85% of US field corn expressing Bt endotoxins, even white corn that is not itself genetically engineered is undoubtedly contaminated by GE corn, given corn’s ability to cross-pollinate at distances of thousands of feet to over a mile in strong winds, and no requirements (like buffer zones) to prevent it. This is exemplified by contamination of white corn with StarLink, despite StarLink corn being grown on minimal acreage prior to being banned for potentially causing food allergies.

### Industrial GE Biofuels Corn

One lesson from the StarLink episode was to never again issue “split approvals” for a GE crop (for feed/industrial but not food use), especially one that poses potentially serious health risks. The lesson did not stick. In 2011, the USDA deregulated (approved) Enogen – corn genetically engineered as a feedstock for ethanol plants – relying entirely on the corn’s developer, Syngenta, to keep it out of the food supply.<sup>34</sup> USDA’s approval came without requiring any isolation measures to prevent contamination of non-Enogen corn.

Enogen was deregulated despite the clear potential for its alpha-amylase enzyme to cause allergies, given its allergenic characteristics: resistance to digestion, stability at high

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<sup>28</sup> Freese and Schubert (2004), op. cit., pp. 308-310. See also: Gendel S (1998). The use of amino acid sequence alignments to assess potential allergenicity of proteins used in genetically modified foods,” *Advances in Food and Nutrition Research* 42: 45-60.

<sup>29</sup> Friends of the Earth, Comments to EPA concerning the revised risks and benefits sections for *Bacillus thuringiensis* plant pesticides, Sept. 10, 2001 (revised version Sept. 21, 2001).

<sup>30</sup> FAO-WHO (2001). Evaluation of allergenicity of genetically modified foods. Report of a joint Food and Agriculture and World Health Organization expert consultation, January 22-25-2001. [https://www.fao.org/fileadmin/templates/agns/pdf/topics/ec\\_jan2001.pdf](https://www.fao.org/fileadmin/templates/agns/pdf/topics/ec_jan2001.pdf).

<sup>31</sup> DiFonzo C (2023). The Handy Bt Trait Table, updated 2/2/23. [https://www.texasinsects.org/uploads/4/9/3/0/49304017/bttritable\\_feb\\_2023.pdf](https://www.texasinsects.org/uploads/4/9/3/0/49304017/bttritable_feb_2023.pdf).

<sup>32</sup> 40 C.F.R. Part 174.500 to 174.542, Subpart W: Tolerances and Tolerance Exemptions. <https://www.ecfr.gov/current/title-40/chapter-I/subchapter-E/part-174>.

<sup>33</sup> Thus far, EPA has performed cumulative risk assessments of just five groups of chemical pesticides. See <https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/cumulative-assessment-risk-pesticides>.

<sup>34</sup> Roseboro K (2011). Starlink 2? Approval of GM biofuel corn threatens food supply. *The Organic and Non-GMO Report*, March 1, 2011. <https://tinyurl.com/2u3zf6kzt>.



temperatures, and amino acid homology to a known allergen; the approval also came against the recommendations of leading food allergists.<sup>35</sup> After two in-depth reviews, the European Food Safety Authority continues to be concerned by the potential allergenicity of Enogen's alpha-amylase enzyme.<sup>36</sup>

Enogen poses food quality as well as allergenicity concerns, and faced opposition not only from public interest groups, but also from major trade organizations representing corn processors<sup>37</sup> and grain traders, who warned that even low-level contamination of corn supplies with Enogen – as little as 1 kernel of Enogen in 10,000, or 0.01% – would ruin masa corn products made from it.<sup>38</sup> The starch-degrading activity of alpha-amylase results in soupy corn grits, crumbly cornbread and sticky tortillas.<sup>39</sup>

Just like FDA in its voluntary consultations on GE foods, however, USDA uncritically accepted all aspects of Syngenta's assessment. In filings with USDA, Syngenta downplayed the risk that Enogen corn would contaminate other corn varieties. Syngenta relied heavily on a dubious study that incorporated a 200-meter buffer zone around Enogen corn, despite ample evidence of corn cross-pollinating at far greater distances.<sup>40</sup> Once Syngenta had obtained USDA approval, however, Enogen has been grown across the country with an entirely inadequate 30-foot buffer zone from neighboring corn. Small wonder that the Vice President of the normally pro-biotech North American Millers Association, Jim Bair, described U.S. government regulation of GE crops as “cobbled together with bailing wire and duct tape.”<sup>41</sup>

As predicted, Enogen has widely contaminated the U.S. corn supply. Based on the limited information that is available, growers of white corn in Nebraska, the country's number one producer of white corn, have been hit hardest.<sup>42</sup> Enogen contamination is described as a “trainwreck” and a “nightmare” that has affected numerous farmers, including one who was forced to abandon 25,000 bushels of Enogen-tainted white corn.<sup>43</sup> Farmers worry that increasing Enogen cultivation will force them to stop growing white corn altogether. The map below (at <https://ip360.agconnections.com/>, multiply by 1000 for numbers followed by “k”) shows that Enogen is being grown throughout the U.S. and southern Canada.

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<sup>35</sup> CFS (2009). Comments to USDA APHIS regarding Syngenta Seeds' Alpha-Amylase Maize Event 3272 (Enogen), Docket APHIS-2007-0016, Jan. 20, 2009, pp. 8-16.

[https://www.centerforfoodsafety.org/files/cfs\\_comments\\_on\\_biofuel\\_corn\\_1-20-09.pdf](https://www.centerforfoodsafety.org/files/cfs_comments_on_biofuel_corn_1-20-09.pdf)

<sup>36</sup> European Food Safety Authority, Statement complementing the EFSA Scientific Opinion on application for authorization of food and feed containing, consisting of and produced from genetically modified maize 3272, Sept. 25, 2019. <https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/j.efsa.2019.5844>.

<sup>37</sup> Corn Refiners Association, Comments on proposed deregulation of Syngenta Seeds corn Event 3272, Jan. 20, 2009. [file:///Users/billfreese/Downloads/APHIS-2007-0016-0175\\_attachment\\_1.pdf](file:///Users/billfreese/Downloads/APHIS-2007-0016-0175_attachment_1.pdf).

<sup>38</sup> Roseboro, K (2013). Is ethanol GM corn a disaster waiting to happen? The Organic and Non-GMO Report, Oct. 3, 2013. <https://non-gmoreport.com/articles/october2013/ethanol-gm-corn-disaster.php>.

<sup>39</sup> EnviroLogix (2022). Case study: high-sensitivity testing for Enogen corn. EnviroLogix, April 8, 2022. <https://www.envirologix.com/news/high-sensitivity-enogen-case-study/>.

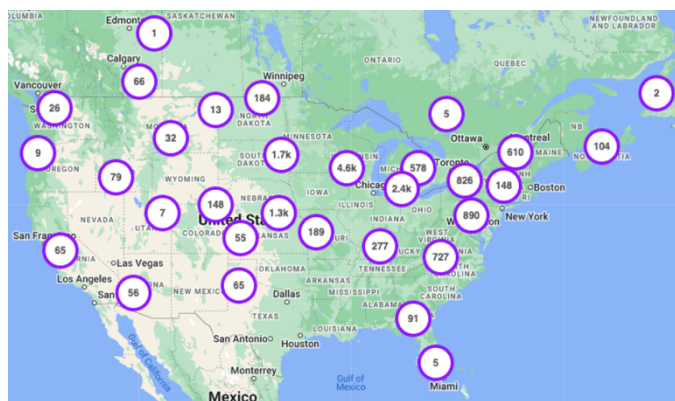
<sup>40</sup> CFS (2009). Comments to USDA APHIS regarding Syngenta Seeds' Alpha-Amylase Maize Event 3272 (Enogen), Docket APHIS-2007-0016, Jan. 20, 2009, pp. 28-35.

<sup>41</sup> As quoted in: Roseboro K (2013), op. cit., ft. 38.

<sup>42</sup> Brownfield Ag News, Enogen vs. food grade: a coexistence issue in Nebraska, January 19, 2018. <https://brownfieldagnews.com/rural-issues/enogen-vs-food-grade-coexistence-issue-nebraska/>.

<sup>43</sup> Roseboro K (2017). GMO-ethanol corn contamination raises concerns about another “StarLink” disaster, The Organic & Non-GMO Report, Feb. 22, 2017. <http://tinyurl.com/5n7w9jch>.

As critics predicted, Enogen has been detected in white maize products made from contaminated maize. Tamales made from masa flour purchased from Amapola Market, a Hispanic grocery chain in Los Angeles, turned out gooey, fell apart, and even made people sick.<sup>44</sup> The problem, which affected thousands of people, was traced back to a 120,000 pound shipment of white corn delivered to Amapola in December 2016. While Enogen testing was not conducted in this instance, Enogen-contaminated corn flour has caused just such problems in other cases.<sup>45</sup>



### Other unknown varieties of GE corn

As discussed above, the broad “deregulation” of GE crops in the U.S. means that many GE maize varieties with unknown traits are likely being grown, without tracking or safety assessment. The U.S. has become a lawless “Wild West” for biotech crops, and Mexico is fully justified in restricting imports of maize from the U.S. to protect its citizens and environment.

## **U.S. Maize and Glyphosate**

### Cancer and other health hazards of glyphosate

In 2015, the world’s premier authority on carcinogens, the World Health Organization’s International Agency for Research on Cancer (IARC), classified glyphosate as probably carcinogenic to humans.<sup>46</sup> Roundup users with non-Hodgkin lymphoma (NHL), the cancer linked to glyphosate in epidemiology studies, have won numerous lawsuits against Monsanto affirming that Roundup was a factor in the development of their cancers.<sup>47</sup>

Center for Food Safety and allied groups sued EPA for its unlawful registration review decision re-approving glyphosate. We focused on EPA’s flawed human health assessment that dismissed the cancer risks found by IARC and other independent scientists. In its decision, the Ninth Circuit Court of Appeals agreed with plaintiffs, and took the unprecedented step of rescinding EPA’s human health assessment of glyphosate.<sup>48</sup> Among other findings, the Court noted that EPA conceded a possible link between glyphosate and NHL, yet nevertheless misclassified glyphosate in a category (“not likely to be carcinogenic”) that requires robust evidence that glyphosate does **not** cause cancer. The Court found that this blatant inconsistency, together with EPA’s numerous violations of its own guidelines for assessing a pesticide’s cancer risk, invalidated its human health assessment of glyphosate.<sup>49</sup>

<sup>44</sup> Ibid.

<sup>45</sup> Ibid.

<sup>46</sup> Guyton KZ et al. (2015). Carcinogenicity of tetrachlorvinphos, parathion, malathion, diazinon, and glyphosate. *Lancet* 16(5): 490-491.

<sup>47</sup> Gaines M (2024). Roundup lawsuit update: March 2024. *Forbes Adviser*, Feb. 2, 2024.

<https://www.forbes.com/advisor/legal/product-liability/roundup-lawsuit-update/>

<sup>48</sup> CFS (2022). Federal court rejects glyphosate registration decision because EPA ignored cancer risks, endangered species risks, Center for Food Safety, June 17, 2022. <https://tinyurl.com/2dds8kb5>.

<sup>49</sup> For the court’s decision, see: [https://www.centerforfoodsafety.org/files/ca9\\_glyphosate-decision\\_82995.pdf](https://www.centerforfoodsafety.org/files/ca9_glyphosate-decision_82995.pdf).

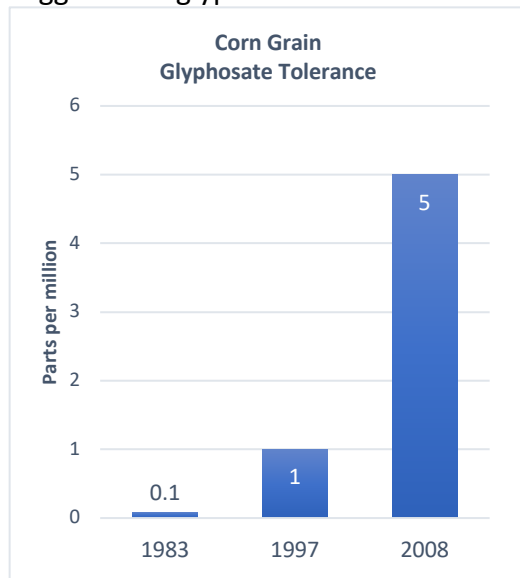


EPA's pesticide division has clearly deviated from the science in a failed attempt to whitewash the image of glyphosate as safe. CFS and allied groups recently petitioned EPA to cancel registrations of glyphosate based on its clearly biased and unscientific cancer assessment as well as its deeply flawed assessments of other human health and environmental risks.<sup>50</sup> These adverse health effects take on added significance in light of the massive increase in glyphosate use and exposure over the past three decades.

### Glyphosate Use and Exposure

Glyphosate became the world's leading herbicide with the growing dominance of genetically engineered (GE), glyphosate-resistant varieties of soybeans, cotton, maize, sugar beets, canola and alfalfa. Introduced in 1996, GE glyphosate-resistant maize varieties represented 91% of all acres planted to maize in the U.S. in 2023.<sup>51</sup> Each year nearly 100 million lbs. of glyphosate are applied to U.S. maize, which represents the most intensively sprayed crop, accounting for 35% of total agricultural glyphosate use of 275.2 million lbs/year.<sup>52</sup>

Whether glyphosate causes cancer or other health harms depends in part upon how much enters the body. While farmers and other glyphosate applicators are thought to have the highest exposure, some studies that find equivalent levels in farm and non-farm families suggest that glyphosate residues in food is a major exposure pathway.<sup>53</sup>



Glyphosate residues in maize increased dramatically with the introduction of Roundup Ready maize, which is sprayed directly with glyphosate. Preharvest glyphosate use also leads to higher residues. To accommodate these higher residues, the EPA has raised the “tolerance” – known outside the U.S. as the maximum residue level (MRL) – for glyphosate in or on maize grain by an enormous 50-fold over the past three decades (see graph). The tolerance was raised 10-fold – from 0.1 parts per million (ppm) to 1.0 ppm – in 1997.<sup>54</sup> It was raised again by five-fold to 5 ppm in 2008.<sup>55</sup> EPA has also granted Monsanto's requests to raise glyphosate tolerances on wheat, oats and a host of other crops.<sup>56</sup>

USDA found glyphosate residues in over 30% of maize from Missouri in 2021/2022.<sup>57</sup> FDA detected glyphosate in 63% of maize samples it tested in 2016, though the agency did not report either residue levels or the sensitivity of the

<sup>50</sup> CFS (2023). Farmworkers, environmental groups file legal action demanding Roundup ban. Center for Food Safety, Dec. 13, 2023. <https://tinyurl.com/mwa7cr7w>.

<sup>51</sup> USDA, Adoption of Genetically Engineered Crops in the U.S., <https://tinyurl.com/mrkv88y7>. 91% is sum of “herbicide-tolerant” and “stacked” percentages.

<sup>52</sup> U.S. Geological Survey, Glyphosate Use by Year and Crop, <https://tinyurl.com/3mc5wnr3>.

<sup>53</sup> Curwin BD et al. (2007). Urinary pesticide concentrations among children, mothers and fathers living in farm and non-farm households in Iowa. *Ann. Occup. Hyg.* 51(1): 53-65.

<sup>54</sup> For 0.1 ppm, see EPA memo (8/20/96) at <https://tinyurl.com/3pdksnby>; for increase to 1 ppm, see Federal Register notice (4/11/97) at <https://tinyurl.com/42yfvuw9>.

<sup>55</sup> See Federal Register notice at <https://tinyurl.com/4pbvyxvb>.

<sup>56</sup> For a full list of current glyphosate tolerances, see: <https://tinyurl.com/mr3p9rtx>.

<sup>57</sup> Based on 3/12/24 search of USDA's Pesticide Data Program database, at <https://apps.ams.usda.gov/pdp.3/12>.

test.<sup>58</sup> Unfortunately, FDA mysteriously dropped glyphosate from its testing program after 2016, despite years of work to develop and validate an assay.<sup>59</sup> Meanwhile, USDA has tested for glyphosate residues in maize only once (2021/2022), and otherwise only in soybeans (2011/2012, 2021/2022), since it began its Pesticide Data Program (PDP) in 1991. An independent group commissioned tests finding glyphosate residues in Kellogg's corn flakes and other breakfast foods.<sup>60</sup> Thus, it is not surprising that Mexican researchers have also detected glyphosate in commercial maize flour, cereals, tortillas and snacks.<sup>61</sup>

The paucity of data for maize and other foods makes it impossible to determine the glyphosate dietary exposure level of either U.S. or Mexican residents. However, EPA has periodically made upper-bound estimates of exposure to glyphosate in a typical U.S. diet. Based on these estimates, high-end exposure of the general population has increased by 12-fold since 1983, while the upper-bound exposure of infants and toddlers has risen four-fold since 1993.<sup>62</sup>

To accommodate the increased exposure from these higher residues, EPA has raised the glyphosate safety threshold by 20-fold since the late 1970s. This safety threshold is the maximum daily exposure level that EPA regards as safe over a lifetime, based on animal studies. EPA originally set the threshold at just 0.05 mg/kg bw/day based on fatty liver effects of glyphosate in a two-year rat feeding study; then raised it to 0.10 mg/kg bw/day based on a different study showing glyphosate damages kidney tubules. EPA concocted reasons to dismiss these studies and the associated adverse effects, and then raised the safety threshold by 20-fold, to 2 mg/kg bw/day, in 1993, which paved the way for introduction of glyphosate-resistant crops two years later; the threshold was lowered to 1 mg/kg bw/day in 2017.<sup>63</sup>

## Conclusion

Mexicans consume far more maize – 0.5 kg/day<sup>64</sup> – than North Americans. For instance, EPA estimated Hispanic children 7-12 years of age in the U.S. would have many times the exposure to StarLink's Cry9C as U.S. citizens,<sup>65</sup> and the same of course holds for any transgenic proteins and glyphosate residues in or on GE maize. In view of this vastly greater exposure, as well as the U.S. abdication of regulatory control over GMOs and glyphosate, and the known and suspected human health hazards they pose, Mexican authorities are entirely justified in restricting imports of GE corn from the U.S. to protect the health of their citizens.

Bill Freese, Science Director  
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<sup>58</sup> FDA, Pesticide Residue Monitoring Program: Fiscal Year 2016 Pesticide Report, Table 6b, p. 28. <https://www.fda.gov/media/117088/download?attachment>.

<sup>59</sup> Gillam C (2017). FDA suspends testing for glyphosate residues in food. HuffPost, Dec. 6, 2017. [https://www.huffpost.com/entry/fda-suspends-glyphosate-r\\_b\\_12913458](https://www.huffpost.com/entry/fda-suspends-glyphosate-r_b_12913458)

<sup>60</sup> Food Democracy Now, Glyphosate: Unsafe on any plate, 2016. <https://tinyurl.com/yw4s2m9c>.

<sup>61</sup> Gonzalez-Ortega E et al. (2017). Pervasive presence of transgenes and glyphosate in maize-derived food in Mexico. *Agroecology and Sustainable Food Systems* 41(9-10): 1146-1161.

<sup>62</sup> CFS (2019). Comments on Glyphosate Proposed Interim Registration Review Decision, Center for Food Safety submission to EPA Docket EPA-HQ-OPP-2009-0361, Sept. 3, 2019, pp. 15-17. <https://tinyurl.com/ynr8pcrf>.

<sup>63</sup> Ibid., pp. 12-14. Note that "mg/kg bw/day" means milligrams of glyphosate per kilogram body weight per day.

<sup>64</sup> Gonzalez-Ortega et al. (2017), op. cit.

<sup>65</sup> Bucchini and Goldman (2002), op. cit., p. 9.