

The United States do not exempt GMOs/NGTs

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Unlike the European Union, in the United States, GMOs produced using new techniques of genetic modification (NGTs) are subject to federal legislation on GMOs. They may be subject to a risk assessment and, since 2018, to labelling and traceability requirements. Although the US administration sought to deregulate them in 2020, a court ruling in December 2024 cancelled this exemption.



Institute for progress

It was in 1987 that the US administration adopted the legislation governing the commercial release of genetically modified plants produced by one or more "*techniques that use recombinant, synthesized, or amplified nucleic acids to modify or create a genome*"¹. Whilst amendments have been made since then, the general principle has remained the same: to determine whether the genetically modified organism poses a risk of being or becoming a plant pest.

The basic principles of the regulatory framework for GMOs

An initial assessment is carried out by the authorities, based on a dossier submitted by the applicant providing a description of the plant, the genetic modification, the new characteristic and the biochemical process through which the modification induces this new characteristic. This initial assessment aims to establish whether the modified plant is already recognised as a "*pest*" or may become one, and whether the modified genetic sequence originates from a "*pest*" organism. If the answer to each of these three questions is "*no*", the GMO is then declared "*not regulated*" and may be placed on the market. If any one of the three answers is "*yes*", the US authorities then carry out a risk assessment, which may conclude that the GMO should be regulated or that it should not be regulated.

One should not assume that the United States carries out no assessments at all. To address questions regarding whether or not a GMO is a "*pest*", the Department of Agriculture seeks to answer several questions, including those concerning the potential impacts on non-target organisms and agricultural biodiversity, and the potential for a GMO to become invasive, amongst others. If the GMO is initially classified as "*regulated*", a more in-depth environmental risk assessment is carried out.

The Food and Drug Administration (FDA) is responsible for assessing health risks. On the basis of discussions with the applicant and in addition to the information characterising the GMO, this ministry requests data concerning the effects of the genetic modification on the nutritional composition and characteristics of the organism (compared with the non-GMO parental variety), on the quantity of all expressed products, and data on the allergenicity and toxicity of these productsⁱⁱ, etc.

Since 2018, mandatory labelling and detection for GM food

It should be noted that a law passed in 2016 made labelling compulsory for GMOs intended for human consumption and designated as regulated following assessments carried out by the various ministriesⁱⁱⁱ. This rule has been fully applicable to all processors and importers since 2022.

Alongside this labelling requirement, analytical detection of GMOs has also become mandatory^{iv}. These methods, regulated by the Ministry of Agriculture^v, are not necessarily required for all products, as processors who can, for example, demonstrate that there is no longer any modified genetic material in their products are exempt from this requirement. Indeed, the legislation making labelling mandatory stipulates that it is not required for "*a food in which no ingredient intentionally contains a bioengineered [Editor's note: genetically modified] substance, with an allowance for inadvertent or technically unavoidable BE presence of up to five percent (5%) for each ingredient*"^{vi}. In such cases, records (such as registration documents, certificates, etc.) must still be kept.

Where labelling is required, it is worth noting that the question of whether or not genetic modifications are detectable does not arise. The Ministry of Agriculture has even produced a document setting out the various accepted methods, which also includes "*emerging technologies [when] become more commercially and economically accessible*"^{vii}.

The exemptions adopted in 2020

The timing is undoubtedly no coincidence, as it was before these obligations came fully into force in 2022 that the US administration, under the presidencies of Donald J. Trump and subsequently Joe Biden, adopted rules exempting certain GMOs, regardless of their use or intended purpose. The principle was to introduce a preliminary stage prior to determining whether a GMO is "*regulated*" or "*not regulated*". Whilst the administration's work on this status is carried out on a case-by-case

basis, at the request of a petitioner, the administration established in 2020 that certain GMOs would not have to go through this stage, declaring them exempt as a matter of principle.

As the US Congress points out, this procedural change took place against a backdrop where "*biotechnology techniques have evolved (e.g., newer genome-editing methods, such as CRISPR/Cas9). These developments prompted debate over whether certain genome-edited plants should be regulated in the same manner as earlier transgenic organisms*"^{viii}.

In practice, as explained by the US administration in responses provided to the OECD in 2025^{ix}, several exemptions were adopted from 2019 onwards for plants modified using NGT. By definition, therefore, the following were exempt from regulatory oversight:

- plants modified by recombinant DNA techniques (GMOs), but which "*re achievable through conventional breeding techniques and thus are unlikely to pose an increased plant pest risk compared to conventionally bred plants*";
- or genetically modified plants with a "*plant-trait-mechanism of action combination*" identical to that of a plant which the Ministry of Agriculture had previously declared to be "*unlikely to pose plant pest risk*".

The exempted plants were therefore those containing a modification of the following types:

- "*a change resulting from cellular repair of a targeted DNA break in the absence of an externally provided repair template*";
- *a targeted single base pair substitution*;
- *a gene known to occur in the plant's gene pool, or a change in a targeted sequence to correspond to a known allele of such a gene or to a known structural variation present in the gene pool*;
- *an indel [an insertion/deletion] or contiguous deletion of any size, made at a targeted location, with or without insertion of DNA if generated without using a repair template, or without insertion of DNA if generated using a repair template*'.

Genetically modified plants intended for food use that met one of the above criteria therefore did not even need to go through the "*is the GMO regulated or not?*" stage, as the exemption was a prerequisite for the regulatory procedure.

A court ruling overturning these exemptions

On 2 December 2024, however, a ruling by the Northern District Court of California^x was to change the situation. As the judge noted in his ruling, the exemption adopted in 2020 was based on the assumption that GM plants, which can also be produced using conventional breeding techniques, do not pose any greater risks than the latter.

According to the December 2024 judgement, this assertion was not sufficiently substantiated by scientific evidence to support the decision to grant the exemption. The judge emphasised in particular that the scientific report used by the administration, dating from 2002, had been contradicted by other scientific data published since then, thereby casting doubt on this assertion of equivalence between the methods used to produce the products and the presence of risks. Whilst the judge stated that the authorities are entirely free to decide to exempt certain GMOs from the regulatory framework, they must, in doing so, provide "*adequate explanation and support for its determinations*".

This issue of scientific data supporting a decision to deregulate GMOs/NGTs is reminiscent of the situation in Europe, where the legislator based its decision to deregulate on the same argument. In the preamble to EU Regulation 2026/1388, it is indeed noted that *"NGT plants that could also occur naturally or be produced by conventional breeding techniques ("category 1 NGT plants") should be treated in the same way as plants that have occurred naturally or have been produced by conventional breeding techniques, given that they are equivalent and that their risks are comparable"*. A notable difference: the European legislator did not take care to refer to scientific opinions or data in support of this assertion in the adopted regulation. *Inf'OGM* will return to this in a future article.

What happens next?

Taking note of the decision of 2 December 2024, the USDA announced on 19 December 2024^{[xi](#)} that it would resume the regulatory process for GMOs and NGTs with effect from 8 January 2025. It specifies, however, that this procedure is not retroactive and that all confirmations of non-regulation issued prior to 2 December 2024 remain valid.

To date, therefore, the United States does indeed regulate GMOs/NGTs, and furthermore requires labelling and detection methods for those intended for food use and designated as *"regulated"*. But the file may not end there. As the US Congress notes, the USDA has already issued *"an anticipated interim final rule titled "Regaining Lost Efficiencies for Products of Biotechnology" (RIN 0579-AE84), indicating that USDA intends to alter regulatory processes following the vacatur of the SECURE rule"*. Whilst Congress states that this draft legislation was discussed at the annual meeting of biotechnology regulatory agencies in February 2026, it adds that it has not been published and that its details are not yet available. Congress does, however, specify that *"exemptions or simplified procedures for certain low-risk plants and micro-organisms, including some commonly used in laboratory development"* would be considered.

Paradoxically, the definition of NGT1 plants – which are almost entirely deregulated under the new European NGT regulation adopted in June 2026^{[xii](#)} – draws heavily on the US deregulation criteria that were overturned in December 2024 by the Northern District Court of California. This could create barriers to European exports to the United States... unless this invalidation were in turn overturned by new US legislation.

ⁱ USDA, [« Guide for Requesting a Regulatory Status Review under 7 CFR part 340 »](#), 20 December 2022.

ⁱⁱ FDA, [« Guidance for Industry: Consultation Procedures under FDA's 1992 Statement of Policy for Foods Derived from New Plant Varieties »](#), October 1997.

ⁱⁱⁱ USDA, [« BE Frequently Asked Questions – Disclosure »](#).
USDA, [« List of Bioengineered Foods »](#).

^{iv} Agricultural Marketing Service, Department of Agriculture, [« National Bioengineered Food Disclosure Standard – 7 CFR 66.9 »](#), 21 December 2018.

^v USDA, [« Frequently Asked Questions: Guidance on Testing Methods »](#).

^{vi} Agricultural Marketing Service, Department of Agriculture, [« National Bioengineered Food Disclosure Standard – 7 CFR 66.5 »](#), 21 December 2018.

vii USDA, [« National Bioengineered Food Disclosure Standard Guidance on Testing Methods »](#), 7 July 2020.

viii USA Congress, Bickell, Eleni G., [« USDA's Regulation of Agricultural Biotechnology »](#), 3 March 2026.

ix Eric Meunier, [« The OECD highlights disparities in regulations on GMOs obtained by NGTs »](#), *Inf'OGM*, 24 September 2026.

x UNITED STATES DISTRICT COURT NORTHERN DISTRICT OF CALIFORNIA, [« Case No. 21-cv-05695-JD »](#), 12 February 2024.

xi Aphis, [« APHIS Restarts Permitting and Am I Regulated Processes for Products of Biotechnology »](#).

xii Eric Meunier, [« The deregulation of the GMO/NGT adopted in Strasbourg »](#), *Inf'OGM*, 26 June 2026.

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