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The OECD highlights disparities in regulations on GMOs obtained by NGTs

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The argument that the European Union must catch up with other countries by deregulating GMOs produced using new genetic modification techniques (GMOs/NGTs) is repeated ad nauseam by their proponents. However, at the end of 2025, an OECD report reviewed the legislation in force in some of the largest GMO-producing countries (Argentina, Brazil, Canada, the United States, etc.). And the least one can say is that the international legislative landscape is highly varied.

In 2025, the Organisation for Economic Co-operation and Development (OECD) sent a questionnaire to its members, accession candidates and key partners. This questionnaire concerned the regulation of GMOs produced using new techniques of genetic modification (GMOs/NGTs). In October 2025, it published the twenty responses received[1]. Of the respondents, eleven are members of the European Union (EU) and all referred to the response they had provided before the legislation deregulating these GMOs was adopted. Eight non-EU countries also responded: Argentina, Australia, Brazil, Canada, Japan, South Korea, South Africa and the United

States. This therefore provides an opportunity to take stock of the existing legislation – or lack thereof – in these countries, even though the level of detail in the responses received varies from one country to another.

A limited questionnaire

In its report, the OECD sets out several objectives for its questionnaire. It aimed to collect "*public and official information on regulatory frameworks and approved/registered/reported/notified products of*" new techniques of genetic modification. The OECD requested that products developed solely for research purposes, products currently undergoing the authorisation process, and regulatory frameworks currently under review (considered "*confidential*") be excluded. Genetic forcing technologies are also excluded, as they are "*out of the scope because it is accompanied with insertion of transgenes*", that remain in the organism. Finally, only plants are supposed to be the subject of the requested information, although "*delegations are free to provide information related to other organisms*".

South America (Argentina and Brazil)

Argentina

For Argentina, a candidate for OECD membership, a change in approach was implemented in 2021 following a legislative review process that began in 2020. The country has chosen to regulate GMOs/NGTs by focusing on the question of whether they should be classified as GMOs or non-GMOs. In its response to the OECD, Argentina explains that a procedure has been put in place to address this question. Based on the definition of a living modified organism as set out in the Cartagena Protocol and led by the National Advisory Commission on Agricultural Biotechnology (Conabia), this procedure is designed to determine whether the GMO/NGT is a "*living organism that possesses a novel combination of genetic material obtained through the application of modern biotechnology*". However, Argentina differs from the Protocol in that it also provides a definition of what it considers to be a novel combination of genetic material. For Argentina, such a combination is "*change produced in the genome of the organism by the incorporation, in a stable and joint form, of one or more genes or nucleic acid sequences that form part of a defined genetic construct*". In other words, GMO status is linked to the presence in the genome of a genetic sequence that has been stably inserted. Other modifications (deletions, substitutions, etc.) would not confer GMO status.

Brazil

In 2018, Brazil, a key partner of the OECD, clarified its approach to GMOs and NGTs. As in Argentina, the National Technical Commission on Biosafety (CTNBio) assesses on a case-by-case basis whether GMOs produced using "*innovative Precision Breeding Techniques*" constitute GMOs under Brazilian law. These techniques are defined as "*a set of new methodologies and approaches that differ from the genetic engineering strategy by transgenics, as they result in the absence of recombinant DNA/RNA in the final product*". Five criteria have therefore been established to determine, on a case-by-case basis, whether a product is a GMO or not. If any one of the five criteria is met, the GMO in question will not be legally considered a GMO and will therefore not be subject to the requirements of Brazilian legislation on GMOs.

Thus, the following will not be considered a GMO:

- « *i) Product with proven absence of recombinant DNA/RNA, obtained by a technique that uses GMO as parental;*
- *ii) Product obtained by a technique that uses DNA/RNA that will not multiply in a living cell;*
- *iii) Product obtained by a technique that introduces site-directed mutations, generating gain or loss of gene function, with the proven absence of recombinant DNA/RNA in the product;*
- *iv) Product obtained by a technique where there is expression, temporarily or permanently, of recombinant DNA/RNA molecules, without the presence or introgression of these molecules in the product; and*
- *v) Product where techniques are used that employ DNA/RNA molecules that, whether absorbed or not in a systemic way, do not cause permanent modification of the genome* ».

North America (Canada and the United States)

Canada and the United States, both members of the OECD, have historically taken a different approach to the rest of the world. For these countries, the issue is not whether a product is genetically modified or not.

Canada

Canada focuses on "*novel products*", *i.e.* those with new characteristics or which are, in fact, new foods and therefore different from what is already available in Canada. Where a product is genuinely novel, Canada assesses, for example, the safety of plants with a view to their release into the environment, as well as their safety and efficacy as food for animals and humans. This assessment is based on a dossier submitted by the company wishing to market this novel food. As regards NGTs, they are considered by Canada to be GMOs[2]. However, this GMO status does not specifically alter the approach adopted, which is based on the final product and the question of its novelty. There is, nevertheless, one exception: where release into the environment is envisaged, "*plants with DNA from genetic sources outside the plant species (foreign DNA) and plants with new herbicide tolerance traits are always considered to be novel*"[3].

In the field of environmental release, novelty is assessed in Canada by first considering whether "*the trait is new to cultivated populations of the species in Canada*", and then whether "*the plant has a potential to have a significant negative environmental effect*"[4]. To put it another way, the assessment considers whether the new trait could give rise to "*weediness*", lead to gene flow to compatible plants, cause the plant to act as a parasite, or have an impact on non-target organisms or biodiversity.

For food intended for human consumption derived from genetically modified plants, Canada has established that certain genetic modifications would not confer "*novel*" status, namely if the modification does not render a plant protein allergenic or toxic, does not increase the effects of known allergens or toxins, does not affect "*key nutritional composition and/or metabolism*", does not alter the plant's use as food, or does not involve the presence of foreign DNA in the plant[5].

United States of America

The United States takes a similar approach to Canada, although it is based on a different concept. With regard to release into the environment, the US considers whether the GMO is a pest, could become a pest, or contains DNA derived from a pest. If the answer is no, the organism is "*not regulated*", regardless of the genetic modification technique used.

Between 2020 and 2 December 2024, however, exemptions were granted. These allowed certain GMOs to be exempt from the regulations in force. These exemptions applied to organisms with:

- " *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*".

This exemption also applied to plants with "*up to twelve modifications, made simultaneously or sequentially, if each modification individually qualifies for exemption and occurs in a different gene*" or "*a plant-trait-mechanism of action combination that has been previously reviewed for risks to plant health and determined [...] not to be regulated*".

However, since a court ruling on 2 December 2024 by the US Federal Court in California[6], these exemptions no longer apply and GMOs/NGTs are all regulated in the same way as any other GMO.

Asia-Pacific (Japan, South Korea and Australia)

Japan

In Japan, an OECD member, legislation was revised from 2019 onwards, and gradually thereafter, to address the issue of regulating GMOs produced using "*genome editing technology*". In its response to the OECD, Japan refers to the Cartagena Protocol to determine whether an organism is a GMO or not (the Protocol refers to "*living modified organisms*", or LMOs). However, the Japanese government's interpretation of the Protocol appears to be a permissive one. The country has chosen to focus on the characteristics of the final product, regardless of the technique used, whereas the Protocol (just like the recently amended 2001 European regulation) defines LMOs not on the basis of their characteristics, but on the basis of how they have been genetically modified. Thus, for Japan, if an organism is genetically modified but no longer contains the genetic sequence(s).

This non-GMO status may be granted subject to the provision of information demonstrating:

- the absence of inserted genetic sequences,
- the method of genetic modification used,
- the modified genetic sequence(s) and their functions,
- the new characteristics obtained, as well as any other new characteristics,
- the intended use of the organism,
- and information on "*possible influences on biological diversity when the organism is used*"[7].

Six ministries are involved, depending on the intended uses, whether in agriculture, forestry, veterinary or human medicines (and gene therapy), agri-food processing, research experiments or "*the production of alcoholic beverages*".

South Korea

In South Korea, a member of the OECD, a legislative proposal was tabled in September 2024 aimed at distinguishing between "*conventional LMOs*" and those produced "*through genome editing*". The aim of this proposal was to establish a differentiated regime between the two categories by exempting GMOs obtained through "*genome editing*" from the requirements of the GMO Act. However, to date, this proposal has not been successful, as discussions in Parliament have been suspended. As they are not exempt, GMOs/NGTs are therefore currently regulated as GMOs in South Korea.

Australia

In Australia, an OECD member country, the deliberations and legislative process were spread out over time, with the final version of the Act adopted in February 2025. To date, several scenarios are taken into account when determining whether a product is classified as a GMO or not[8].

Basically, if an organism is modified by cutting its DNA without any "*genetic*" molecule being used to repair it, that organism is not legally a GMO. If, on the other hand, a DNA sequence is used as a guide or expression cassette – without being integrated into the genome – or for insertion, then the organism is legally a GMO. If "*offspring*" organisms are obtained from a GMO but the inserted or used genetic sequences are no longer present, they are not considered to be GMOs.

Thus, among the techniques that result in GMOs legally defined as such in Australia are oligonucleotide-directed mutagenesis and any technique that utilises or inserts genetic sequences. In the case of RNA interference (where small RNA molecules are injected to bind to a "*complementary*" RNA sequence present in the cell and silence it), Australia has stipulated that this exemption should apply only to techniques using "*short-lived RNAi*"[9]. It therefore specifies that the exemption applies only if "*the introduced RNA cannot lead to the production of infectious agents*" and that "*the organism's genomic DNA sequence cannot be changed by the technique*", whilst changes to DNA methylation are permitted.

In Australia, food appears to have a rather distinctive status, as the definition of GMOs intended for human consumption was amended in September 2025[10]. On this occasion, the approach was more radical, as the government chose to define GM foods by considering only the final product, rather than the technique used. Consequently, any "*an organism or cells containing novel DNA*" is considered to be a GMO.

In view of the definition adopted for "*novel DNA*", Australia has therefore chosen, in relation to food for human consumption, to define a GMO as an organism containing DNA inserted by a technician into the organism or one of its cells; where such DNA originates from a species that is not sexually compatible, or contains a region of DNA that has been previously rearranged or recombined, or which "*is not from an existing species*".

South Africa

In South Africa, a key partner and the only country on the continent to have responded to the OECD questionnaire, a GMO is legally defined as "*an organism the genes or genetic material of which has been modified in a way that does not occur naturally through mating or natural recombination or both*". On the basis of this definition, South Africa replied to the OECD that its Executive Council had concluded that the risk assessment framework applicable to GMOs also applies to GMOs/NGTs. In other words, these are GMOs that must comply with the requirements

laid down by legislation as decided by the government in 2021. As the African Centre for Biodiversity points out11, these legislative requirements therefore mandate the issuance of a marketing or trial authorisation, a risk assessment, labelling, and a method for detection and identification. It adds that, "*sometimes [...] socio-economic and ethical considerations*" are adressed.

Disparate regulations

Looking at the eight non-EU responses, it is clear that the regulatory framework for GMOs/NGTs varies considerably. This contradicts what multinationals and the European Commission have suggested, namely that the EU should deregulate GMOs/NGTs to bring itself into line with other countries. On the contrary, it is possible that the EU's decision will be the one to trigger legislative changes in other countries. Indeed, several have chosen to align themselves with European legislation, as the EU is the world's largest import market.

These differences could also give rise to significant problems in international trade, as well as heated debates within the Cartagena Protocol, of which most of the countries mentioned above are members. Indeed, a majority of the signatory countries to this protocol still regard GMOs/NGTs as GMOs subject to its provisions.

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