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**Report Highlights:**

This report assesses the agricultural biotechnology sector in the Netherlands, and covers related production, trade, and policies. It includes topics related to genetic engineering and innovative plant, animal, and microbial biotechnologies. On July 5, 2023, the European Commission (EC) adopted a new proposal to regulate plants obtained by certain “new genomic techniques (NGTs)” and their use for food and feed. One of the key elements of the proposal is to lift the risk analysis for approval and labeling for the end-consumer of “NGTs” that could also occur naturally. Over the past five years, the Dutch Government position towards the application of “NGTs” has been roughly in line with the content of the current EC proposal. The Dutch Government’s support for the application of “NGTs” is based on the use of these technologies as an important propagation tool for the Dutch plant breeding sector, and a vital technology to improve the sustainability of agricultural production systems.

## **EXECUTIVE SUMMARY**

The Dutch Government and agricultural sector have a pragmatic approach towards the import of genetically engineered (GE) agricultural products. The Netherlands is one of the largest importers of soybeans and soybean derivatives, which serve as an important input for the Dutch European livestock sector. However, domestic crop trials and commercial cultivation of GE crops are effectively prevented by cumbersome regulations and the threat of protests from environmental groups.

The Dutch Ministry of Agriculture, Nature, and Food Quality policy objective is to reach the goals set forth in the Farm-to-Fork (F2F) Strategy<sup>1</sup> via a circular agriculture model with robust crop culture systems, less dependency on pesticides, and the safe use of biotechnology. In the innovation agenda of the Dutch “[Top Sector](#)” (Dutch language) policy, genome editing is identified as one of the key technologies that may be utilized to improve plant pest resistance, nutrient utilization, and biomass yields.

On July 5, 2023, the European Commission (EC) adopted a new [proposal](#) to regulate plants obtained by certain “new genomic techniques (NGTs)” and their use for food and feed. The EC proposes two categories of “NGT” plants:

- Category 1 – “NGT” plants that could also *occur naturally* will be treated like conventional plants and therefore exempted from the requirements of the GMO legislation.
- Category 2 – “NGT” plants that could *not occur naturally* will be treated like GE varieties following the authorization procedure required in the “GMO” framework.

The proposal will now be evaluated by the European Parliament and Council of the EU. Over the past five years, the Dutch Government’s position towards the application of innovative biotechnologies has been roughly in line with the content of the current EC proposal. The current Dutch Cabinet states that the safety for humans and the environment are safeguarded by the EC proposal.

- For Category 1 “NGTs”, the Cabinet supports to lift the labeling for the end-consumer, to enforce labeling the propagation material, and to provide relevant information for the professional user in a database.
- For Category 2 “NGTs”, the Cabinet supports a proportional risk analysis and the inclusion of sustainability criteria for the approval procedure.

In a recent public [policy document](#) (Dutch language) presented to the Dutch Parliament on September 8, 2023, the Cabinet states that the equivalence criteria by which the separation between the two categories is made (as outlined in Annex I of the proposal), are not yet sufficiently clear and proportionate. Furthermore, the Cabinet questions if the exclusion of “NGTs” by the organic sector as well as the freedom of choice to use “NGTs” by other sectors is sufficiently safeguarded by the reference to [Regulation \(EU\) 2018/848](#) on organic production and labelling of organic products. Finally, the Cabinet supports the EC to conduct a study on how the proposal interacts with Intellectual Property Rights (IPR) but wants to obtain the results of this study sooner than 2026 as outlined in the proposal.

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<sup>1</sup> For additional information, see, e.g., [E42020-0028: Green Deal Strategies for the EU Agri-Food Sector Present a Politically Ambitious Policy Roadmap](#)

The Dutch livestock sector does not utilize any GE animals nor do Dutch agricultural research institutes keep them for research purposes. Besides the public’s aversion, also the lack of confidence of Dutch scientists in the potential of the technology is a limiting factor of the commercial uptake of technology. The Ministry of Agriculture, Nature, and Food Quality has stated that the Dutch Government does not oppose the EC proposal to ban food derived from cloned animals, but only if the regulation is practical and in line with international obligations.

Due to its geographical location and infrastructure, the Netherlands is the gateway to Northwestern Europe. Therefore, the Netherlands has a relatively large processing sector, converting agricultural imports into food, feed, and fuels. As part of the [“Top Sectors”](#) (Dutch language) policy, the Dutch Government developed an innovation agenda for microbial (industrial or “white”) biotechnology. The agenda is focused on the conversion of waste streams, production of food and non-food ingredients, and the production of meat and dairy replacers. Genome editing is mentioned as one of the tools that could be utilized to reach these goals. In the Netherlands, research institutions and companies producing dairy and meat replacers have united in the [Cellular Agriculture Netherlands Foundation \(CANS\)](#). The Dutch Government [funds](#) (Dutch language) cellular agriculture with €60 million through the [National Growth Fund](#). The funding will be allocated for research, commercialization, and education of qualified personnel.

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## CHAPTER I: PLANT BIOTECHNOLOGY

### PART A: PRODUCTION AND TRADE

#### a) Product Development

The Netherlands is home to one of the world's leading plant propagation sectors. Given the cumbersome regulations for developing and approving genetically engineered (GE) crops, Dutch plant breeding companies have focused on innovative plant biotechnologies. In the Netherlands, there are no GE crops under development that will be on the market within the next five years. The [database](#) (in the Dutch language) of the National Institute for Public Health and the Environment (known as the RIVM) reports that the most recent license granted for market introduction (listed as MA in the database) of a GE plant was in 2019. The license was requested by a Japanese breeder to market a GE carnation variety. The flower breed contains an herbicide tolerance gene, and a gene which is expressed as a violet color. Based on the assessment report, the RIVM advised to grant the license. The license includes the import and marketing but excludes the cultivation of the flower.

For cultivation (agricultural field tests, listed with the code IM-L), licenses were granted to produce transgenic apples (resistant against scab), and GE potatoes (resistant against phytophthora) in 2011. In 2015, the last license for cultivation was granted, for cis-genic apples (red flesh with a high content of antioxidants). Since 2015, no licenses have been granted for the cultivation of GE plants in the Netherlands. The licenses for the two GE apple varieties and one GE potato variety were used by Wageningen University and Research (WUR) for field trials (for more information see Chapter 1, Part B, sub-paragraph d) Field Testing). The WUR [Research Group on Ornamentals, Tissue Culture, and Gene Technology](#) focuses on developing and implementing the latest plant breeding techniques in ornamental plants. As the potential for GE crops to be commercialized is limited within the EU, the technique of genetic modification is primarily used for gene function analysis or for testing functionality.

#### b) Commercial Production

In the Netherlands, there are no commercial plantings of GE crops, nor is it expected that any GE crops will be commercially planted in the next five years. This expectation is based on limited producer interest, cumbersome regulations for approval, coexistence regulations, and the threat of protests and consumer resistance.

#### *Dutch Position Towards Legislation for National “Opt-out” of Cultivation:*

In the European Council meeting of June 12, 2014, the Dutch Government voted in favor of a Greek proposal, which allows Member States to ban EU-approved GE crop varieties for cultivation on their territory without scientific justification (referred to as the Opt-out legislation). On March 11, 2015, [Directive \(EU\) 2015/412](#) was officially released (for more information, see the [Agricultural Biotechnology Annual – European Union](#), dated December 22, 2017). With regard to this cultivation “opt-out” option, the Dutch Government will determine if it will allow cultivation on a GE-crop-specific basis. The EU Directive is enforced by the Ministry of Agriculture, Nature, and Food Quality (MinAg). The MinAg's judgment for opting out a specific plant species will be made based on a scientific assessment framework and in consultation with a commission of experts.

The Dutch [Rathenau Institute](#) (Dutch language) organized a stakeholder’s dialogue on the set-up of this assessment framework. In a [letter](#) (Dutch language) to the Dutch Parliament dated October 14, 2016, the Dutch State Secretary of Agriculture presented the results of the dialogue and the resultant assessment framework. The framework assesses GE crop varieties on the following elements: (1) freedom of choice for farmers and consumers, (2) compliance with the Dutch coexistence regulations, (3) compliance with pesticide regulations, (4) economic implications for conventional and organic farmers, (5) acceptance by society, and (6) the prospects and advantages the GE crop offers for improving sustainability, food security and consumer benefits.

c) Exports

The Netherlands does not produce or export domestically produced GE crops or products. However, the Netherlands trans-ships imported GE crops and products to other EU Member States and re-exports GE materials to non-EU countries. The trans-shipped and exported GE materials are documented and labeled as required by EU legislation.

d) Imports

The Netherlands imports large quantities of GE crops and derived products, predominantly soybeans. Given the absence of cultivation, the Dutch do not import GE seed. Moreover, imports of GE processed consumer products are small, as these products must be labeled. The Netherlands is one of the largest soybean and soybean meal importers in the world. Soybeans and derivatives are imported from the United States and Brazil and soybean meal is imported from Brazil and Argentina (see table below). The share of these shipments which contain GE material is not registered but estimated to be more than 85 percent.

<b>Imports of Soybeans and Meal, the Netherlands (1,000 MT)</b>						
	<b>2017</b>	<b>2018</b>	<b>2019</b>	<b>2020</b>	<b>2021</b>	<b>2022</b>
<b>Soybeans</b>	3,847	4,280	4,115	4,537	4,162	4,007
-United States	1,888	3,030	1,594	1,582	1,268	1,765
-Brazil	1,140	991	1,799	2,344	2,392	1,801
<b>Soybean meal</b>	3,081	2,724	2,678	2,579	2,486	2,968
-Brazil	2,127	2,044	1,950	1,826	1,593	1,799
-Argentina	660	321	269	319	365	520

The import of soybeans, maize, and rapeseed from North and South America is reliant on the approval of genetically engineered (GE) events by the European Commission (EC). For more information see the [GMO Register](#) of the EC. Due to the tight supply of non-GE and organic soybeans, the Dutch Government signed the European Soya Declaration, which supports European soybean production. For more information, see [NL7021: The Netherlands Signs the European Soya Declaration](#), dated July 24, 2017.

With the goal of reducing the EU’s dependency on imported vegetable proteins, the European Commission (EC) requested EU Member States develop a national protein strategy. On December 22, 2020, the Dutch MinAg presented a [National Protein Strategy](#) (Dutch language) by which it aims to

enhance the cultivation of protein-rich crops over the next five to ten years. In the report, the Dutch Government stated that biotechnology can be a tool for improving the productivity of protein-rich legumes. For more information, see [NL2021-0002: Dutch Ministry of Agriculture Launches National Protein Strategy](#), dated January 19, 2021. The former Dutch Minister of Agriculture, Nature and Food Quality, Henk Staghouwer, outlined the implementation of the National Protein Strategy in a [letter](#) (Dutch language) to the Dutch Parliament on June 3, 2022. While plant breeding is mentioned in the letter as crucial for improving yields of legumes, the use of innovative plant biotechnologies is not cited as one of the key technologies to improve the domestic production of plant proteins. For more information about the Dutch policy related to plant biotechnology see PART B: POLICY.

#### *Dutch Position Towards Legislation for National “Opt-out” of Use:*

The directive for opting out of cultivation was followed by a European Commission (EC) proposal for opting out of use. On April 22, 2015, the EC published a [proposal](#) that would allow EU Member States to restrict or ban the use of GE feed or food on their territory. On June 5, 2015, the Dutch Government informed the Dutch Parliament of their position. The Cabinet strongly criticized the proposal on two basic grounds. The main arguments were that the proposal was not science based and that the implementation would have negative effects on the economy. The Dutch Government made the distinction between opting out of cultivation and opting out of use since cultivating crops is a local activity while restricting the use of crops and derived products has repercussions for trade and impacts the cultivation of crops in other countries. Given the importance of international trade to the Dutch economy, the Dutch Government’s position on this subject is not likely to change.

#### e) Food Aid

The Netherlands is not a food aid recipient country, nor does it provide food aid. Financial aid is given either directly to the recipients, through EU institutions, or through Non-Governmental Organizations (NGOs).

#### f) Trade Barriers

The *slow approval process* for new GE events and impractical EU regulations for the allowed *Low-Level Presence* (LLP) of GE materials in shipments to the EU has significantly affected U.S. exports to the Netherlands -- specifically for corn, corn gluten feed (CGF), and Distiller’s Dried Grains with Solubles (DDGS). *Mandatory labeling* of the presence of GE ingredients in food has led processors to avoid using products of GE crops varieties. This affects the sourcing of vegetable oils, which has resulted in the elimination of soybean oil as a food ingredient.

## PART B: POLICY

#### a) Regulatory Framework

As an EU Member State, the Netherlands has implemented harmonized legislation (for more information see [E42021-0088: Agricultural Biotechnology Annual - European Union](#)) regarding agricultural biotechnology in the following [Dutch legislation](#) (Dutch language):

- [Decision Genetic Modified Organisms / Environment](#) (Dutch language)
- [Regulation Genetic Modified Organisms](#) (Dutch language)

<b>Table of terms</b>			
<b>Legal Term (official language)</b>	<b>Legal Term (in English)</b>	<b>Laws and Regulations where term is used</b>	<b>Legal Definition (in English)</b>
ggo (genetisch gemodificeerde organismen)	Genetically Modified Organisms (GMO)	-Decision Genetic Modified Organisms / Environment -Regulation Genetic Modified Organisms	Organism, other than human beings, whose genetic material has been altered in a manner not possible through natural reproduction or recombination

The following three Ministries are responsible for implementation and enforcement of the regulatory framework for agricultural biotechnology in the Netherlands:

The Ministry of Health, Welfare and Sport (VWS) - The coordinating ministry in the policy-making process in the field of medical and agricultural biotechnology. The VWS is also the central competent authority with responsibility for GE legislation in food.

The Ministry of Infrastructure and Water Management (VROM) - Responsible for implementation and enforcement of legislation regarding living GE plants and animals, such as used in laboratory research and feed trials. The responsible ministerial body is the Bureau for Genetically Modified Organisms (BGGO).

The Ministry of Agriculture, Nature, and Food Quality (MinAg) - Responsible for GE legislation in the feed and seed area. Together with VWS, MinAg plays an important role in the implementation of the EU Traceability and Labeling legislation. MinAg has two bodies responsible for enforcement of the legislation regarding biotech feed and food:

- The Netherlands Food and Consumer Product Safety Authority (NVWA) is responsible for documentation and physical control of food and feedstuff imports entering through Dutch ports.
- The Netherlands Inspection Service for Agriculture (NAK) is responsible for inspection of crops and seed imports into the Netherlands.

The Dutch economy's dependency on trade is the one of the main factors which influences the regulatory decisions in the Netherlands. The Dutch economy is not only benefitted via trade-related services, but also benefits from the close access to imported commodities which serve as inputs for the Dutch food processing and intensive livestock sectors. Regarding the regulatory framework for domestic cultivation of GE crops, however, Dutch politicians are more inclined to follow the sentiments of Dutch society. Current national co-existence regulations practically ban the cultivation of GE events.

The Dutch Parliamentary elections in March 2021 did not result in a single party majority. Therefore, four political parties formed a government coalition. The coalition consists of the Liberal Party ([VVD](#)), Liberal Democratic Party ([D66](#)), Christian Democrats ([CDA](#)), and Christian Union ([CU](#)). In the

[Coalition Accord](#) of the Cabinet (Dutch language – the Accord) of December 15, 2021, no reference is made to innovative plant biotechnologies or genome editing. Furthermore, the Accord focuses on circular agriculture (known in Dutch as “kringlooplandbouw”) to lower agriculture’s impact on the climate and environment. A [detailed plan](#) (Dutch language) and [agenda](#) (in Dutch) for putting this vision of circular agriculture in practice was published on June 19, 2019. In the documents, the MinAg stated to pursue to actualize the current EU “GMO” legislation so that the application of “new genomic techniques (NGTs)” will not be restricted. Earlier, in the [Plant Protection Vision for 2030](#) (in Dutch), it was stated that genome editing is an expeditious technique to improve the disease resistance of plant species. For more information about Dutch policy related to genome editing see e) Innovative Biotechnologies.

Because the Dutch Cabinet fell in July 2023, new parliamentary elections are planned on November 22, 2023. In recent polls, the six largest political parties are: the Liberal Party (VVD), New Social Contract (NSC), alliance of the Green Party and the Labor Party (GL/PvdA), the Farmers Citizens Movement (BBB), Party of the Freedom (PVV), and the Liberal Democratic Party (D66). In their election programs (all in Dutch), the [VVD](#) and [BBB](#) are supportive of agricultural biotechnology and modernizing the EC regulations, leading the way to apply innovative biotechnologies in the agricultural and horticultural sectors. These two parties acknowledge the potential of innovative plant biotechnologies, such as CRISPR-Cas, by improving food safety, sustainability, plant health, and food production. Although [D66](#) is commonly supportive of innovation and supports the commercialization of cell-cultured meat, the party is also a strong supporter of organic and circular agriculture and has expressed concerns about the Dutch “dependency” on GE soy imports. In the election program of the [GL/PvdA](#) alliance, the party states to be a strong supporter of organic agriculture and to adhere to the strict European rules for trans-genetic modification of agricultural crops. GL/PvdA advocates for an EU-wide test for the social value of cis-genic crops, such produced with the CRISPR-Cas technology. In their program, the GL/PvdA also committed to enforce labeling of such crops. The [NSC](#) and [PVV](#) make no reference to agricultural biotechnology.

## b) Approvals

The [Dutch GE approval procedure](#) (Dutch language) follows the EU Directive 2001/18/EC and Regulation 1829/2003/EC. In general, the Dutch Government follows the advice of the European Food Safety Agency (EFSA) in the approval of GE plant varieties.

On February 13, 2023, the Ministry of Infrastructure and Water Management (VROM), presented the report [Safety of Biotechnology](#) (Dutch language) to the Dutch Parliament. The report proposes improvements of the Dutch regulations for conducting confined research on innovative biotechnologies. The authors advise to lift or relax the requirements for specific groups of varieties such as crops bred through cis-genesis. In the accompanied [letter](#), the minister stresses the importance of the reducing the complexity of the regulations.

On June 26, 2023, the VROM informed the Dutch Parliament with a [letter](#) (Dutch language) about the results of Dutch research conducted on the safety of innovative biotechnologies for humans and the environment. Research was conducted on a wide range of applications of gene editing for growing industrial fungi and breeding potatoes. In the letter, the minister explains that the research has not found



any unexpected effects. For more information see the report [Biotechnology and Safety](#) (Dutch language).

#### c) Stacked or Pyramided Event Approvals

The Netherlands implements EU legislation.

#### d) Field Testing

Experimental planting of GE crops is almost impossible in the Netherlands. Crop trials are effectively prevented by cumbersome regulations imposed by the government and by the threat of protests from environmental groups. Currently, there are no field trials of GE crops being conducted in the Netherlands. Information about the field trials can be found on the website of the [Bureau for Genetically Modified Organisms \(BGGO\) \(Dutch language\)](#).

#### e) Innovative Biotechnologies

On July 5, 2023, the European Commission (EC) adopted a new [proposal](#) to regulate plants obtained by certain “new genomic techniques (NGTs)” and their use for food and feed. The proposal comes at the end of a long process started on July 25, 2018, with the ruling of the European Court of Justice (ECJ) determining that organisms created through “NGTs” needed to be regulated as “GMOs” and covered by the EU’s current “GMO” Directive of 2001. The EC proposes two categories of “NGT” plants:

- Category 1 – “NGT” plants that could also *occur naturally* will be treated like conventional plants and therefore exempted from the requirements of the GMO legislation. The proposal indicates that the EC will also establish a public database listing the status of category 1 “NGT” plants.
- Category 2 – “NGT” plants that could *not occur naturally* will be treated like GE varieties following the authorization procedure required in the “GMO” framework. “GMO” labelling will be required.

The proposal will now be evaluated by the European Parliament and Council of the EU. For more information see the GAIN Report - [European Commission Adopts New Regulation for Plants Obtained by Certain New Genomic Techniques](#), published August 11, 2023

#### *Position of the Dutch Government Towards the Regulation of “NGTs”*

Over the past five years, the Dutch Government’s position towards the application of innovative biotechnologies has been roughly in line with the content of the current EC proposal. The Dutch Government support for the application of “NGTs” is based on the use of these technologies as an important propagation tool for the Dutch plant breeding sector, and a vital technology to improve the sustainability of agricultural production systems.

On September 7, 2017, the Dutch Government presented a proposal to the EC and EU Member States which holds the view that plants resulting from “NGTs”, *if they are at least equally as safe* as plants obtained by traditional breeding, should be considered GE crops but should be exempted from the

conditions laid down for GE varieties in Directive 2001/18/EC. For more information see FAS GAIN Report [Dutch Proposal to Legislate NBTs \(New Breeding Techniques\)](#), dated September 29, 2017.

On May 14, 2019, the Dutch Government put the issue of legislating innovative plant biotechnologies on the agenda of the Agricultural and Fisheries (AgriFish) Committee and called upon the EC to examine the current legislation for genetically engineered (GE) crops and products. For more information see [The Netherlands Calls for an Amendment of the “GMO” Directive](#), dated December 10, 2018.

On April 29, 2021, the EC published a report titled, [“Study on the status of new genomic techniques under Union law and in light of the Court of Justice ruling in Case C-528/16.”](#) The study concludes that genome editing can contribute to the objectives of the European Green Deal’s F2F and Biodiversity Strategies, and that the “GMO” Directive is not “fit for purpose” to cover genome editing. For more information see the FAS GAIN Report - E42021-0046: [European Commission Publishes Biotechnology Study](#), published May 21, 2021. Following up on the EC study, and as a first step in the legislative process to regulate innovative biotechnologies, the EC published an [Inception Impact Assessment](#) on September 24, 2021. For more information see FAS GAIN Report - E42021-0070: [European Commission Publishes Roadmap on Legislative Initiative for Plants Produced by Certain Genome Editing Techniques](#), published October 1, 2021.

On September 23, 2022 VROM informed the Dutch Parliament via a [letter](#) (Dutch language, including [an appendix in English](#)) of the Dutch response to EC consultations. The response noted:

- “NGTs” have the potential to contribute to societal challenges, such as food scarcity, climate change and the transition to a sustainable and resilient agri-food system.
- If disproportionate burdens on the admission of “NGT” crops will continue to exist, this will ensure that only large multinationals will be able to put these crops on the market.
- Because the European Food Safety Agency (EFSA) has confirmed that *targeted mutagenesis and cis-genesis are equally safe as conventional techniques*, a risk assessment for plants that have been altered with “NGTs” could be replaced by an approval assessment. This process must verify whether the plant has been obtained through the relevant “NGT” (and whether it is free of foreign DNA sequences).
- The provision of information to the consumer is included in the EU Food Law and in the national Commodities Law (through the principle that the consumer should not be misled). This principle also applies to food obtained from “NGTs”. Therefore, labeling or registration of the traits is necessary.

On June 8, 2023, the Minister of Agriculture, Piet Adema, updated the Dutch Parliament on the position of the Dutch Government towards the current regulation of “NGTs” with a [letter](#) (Dutch language). In the letter, the Minister reiterated the Dutch Government’s standpoint earlier outlined by VROM on September 23, 2022, and added that:

- The freedom of choice must be guaranteed for the organic sector (and consumers) by alternative traceability methods and documentation, labeling, and/or digital solutions.
- Negative side effects of the introduction of “NGTs”, such as an elevated use of pesticides, must be prevented. The Dutch Government’s standpoint is that “NGT” traits by itself are not

sustainable, only the application has this potential, and to prevent negative side-effects the application must be regulated horizontally by EC rules.

On September 8, 2023, the Dutch Cabinet informed the Parliament on their position towards the recent EC proposal for regulating “NGTs” with an official [policy document](#) (Dutch language). The Cabinet states that the Dutch Commission Genetic Modification (COGEM) [concluded](#) (Dutch language) that the safety for humans and the environment are safeguarded by the EC proposal, and that plants obtained by site-directed mutagenesis and cis-genesis are comparable with plants obtained by conventional techniques and can be exempted from the “GMO” legislation. But COGEM also concluded that the safety of plants obtained by intra-genesis is not equivalent with plants obtained by conventional breeding. For Category 1 “NGTs”, the Cabinet supports to lift the labeling for the end-consumer, to enforce labeling the propagation material, and to provide relevant information for the professional user in a database. For Category 2 “NGTs”, the Cabinet supports a proportional risk analysis and the inclusion of sustainability criteria for the approval procedure.

In the document, the Cabinet states that the equivalence criteria by which the separation between the two categories is made (as outlined in Annex I of the proposal), are not yet sufficiently clear and proportionate. Furthermore, the Cabinet questions if the exclusion of “NGTs” by the organic sector as well as the freedom of choice to use “NGTs” by other sectors is sufficiently safeguarded by the reference to [Regulation \(EU\) 2018/848](#) on organic production and labelling of organic products. Finally, the Cabinet supports the EC to conduct a study on how the proposal interacts with Intellectual Property Rights (IPR) but wants to obtain the results of this study sooner than 2026 as outlined in the proposal.

#### *Position of Dutch Scientists Towards the Regulation of “NGTs”*

Wageningen University & Research (WUR) scientists and stakeholders in the Dutch plant breeding sector have discussed different scenarios for revising the EU “GMO” legislation. The stakeholders consider the exemption of certain minor mutations that are ***indistinguishable from natural mutations*** from the “GMO” Directive as the best short-term solution but underlined the importance of new future proof legislation for the longer term. For more information see the article: [Future-Proofing EU Legislation for Genome-Edited Plants: Dutch Stakeholders’ Views on Possible Ways Forward](#), published June 30, 2021.

On September 7, 2022, a group of researchers from the North Carolina State University and the Netherlands’ Wageningen University, among others, [proposed a new framework for regulating GE crops](#) in science. The paper asserted that rather than focusing on the methods behind the creation of a GE crop to determine if testing is needed, an alternative would be to examine the specific new characteristics of the crop itself using genomics. Genomics can create a fingerprint to determine whether the product is ***“substantially equivalent”*** to products already being produced by existing varieties.

#### *Dutch Government Support for Research on Innovative Biotechnologies*

In the State Budget of the Netherlands for 2024, released on September 19, 2023, section [XIV – Agriculture, Nature and Food Quality](#) (Dutch language), the Dutch Cabinet underlines their support for the use of “NGTs” for the development of plant varieties which are more resistant against pests, heat, and drought. The Cabinet regards the proposed EU legislation for NBTs as a good basis for a final agreement.

Since 2011, the Dutch Government has had its “[Top Sectors](#)“ (Dutch language) policy in place. “Agri & Food” and “Horticulture & Plant Propagation” are two of the eleven sectors selected. The focus of the “Top Sectors” policy is on innovation and the application of new technologies. Genomics, bioinformatics, seed technology, and genome editing are listed as a key technology for the horticulture and propagation sector. The goal is to make plant breeding more precise and expeditious (precision breeding). As the use of plant breeding methods is species-specific, research is conducted on a variety of methods such as CRISPR-Cas and targeted recombination.

In the Dutch policy document entitled “[Biotechnology and Breeding](#)”(Dutch language), specific goals for plant breeding are listed, such as improving stress resistance (against pests and salinity), improving the utilization of nutrients, production of bio-based feedstocks (for example, conversion of lignocellulose by fungi), doubling photosynthesis, and increasing the protein and biomass yield (of, for instance, lupines and seaweeds).

One of the EU-level programs is the [CHIC project](#), which explores the application of innovative plant biotechnologies in chicory to produce inulin and other plant-based products. This project has received funding from the [Horizon 2020](#) research & innovation program. Another project which received funding from Horizon 2020, is the [EU-COSMOS](#) project, which studies the breeding of camelina and cramble to produce oleo-chemical products. Both projects use the CRISPR-Cas technology. The Commission enforced an ambitious €100 billion research and innovation program – known as [Horizon Europe](#) – to succeed Horizon 2020. EU institutions set the budget for Horizon Europe at €95.5 billion until 2027.

#### f) Coexistence

In 2004, the Dutch agricultural sector and environmental NGOs agreed on coexistence regulations that were accepted by the Dutch MinAg. The regulations include a liability fund to which all farmers, except organic, need to contribute if GE crops are planted in the Netherlands. Despite the coexistence regulations, GE crops can be banned on a municipal and regional level. Currently, for instance the Dutch city of Nijmegen and the Province of Friesland banned GE crops from being cultivated within their borders.

In a [letter to the Parliament](#) (Dutch language) of September 6, 2021, (former) Minister of Agriculture Carola Schouten replied to concerns outlined by the CDA about the vulnerability of organic potatoes to phytophthora, and how the EC goal of 25 percent organic agriculture could exacerbate the problem. Schouten acknowledged that with CRISPR-Cas and cis-genesis technologies, resistance can be applied quicker to existing potato breeds, but that the organic sector excludes innovative biotechnologies.

An international research team of scientists (WUR and Universities in Bayreuth, Göttingen, Düsseldorf, Heidelberg, and Berkeley) [urged](#) the EU to allow the use of novel breeding techniques and modern biotechnology in organic farming. If not, they feared Europe’s F2F strategy will likely fail to deliver on its promise of moving towards realizing the Sustainable Development Goals. In a [letter to the Parliament](#) (Dutch language) on October 7, 2020, (former) Minister Schouten added that transparency and the “freedom of choice” are important for the organic as well as the conventional sectors. She also stressed the importance of the availability of biotech-free propagation material for the organic sector.

#### g) Labeling and Traceability

The Netherlands implemented EU legislation on labeling and traceability into the [Dutch Food Law](#) (Dutch language). Products containing 0.9 percent or more GE content, per ingredient, must be labeled as a product of biotechnology. Products without GE ingredients can be labeled as “produced without gene technology” (in Dutch: bereid zonder gentechniek) if the product complies with the [Novel Foods Food Law Decision](#) (Dutch language). For more information about the labeling and traceability of novel foods see the [Food and Agricultural Import Regulations and Standards \(FAIRS\) reports of the EU and EU Member States](#).

#### h) Monitoring and Testing

The NVWA is actively testing feed and food imports for the presence of GE materials. The Dutch regulations for labeling, sampling, and testing are based on EU legislation. The marketing of crop varieties produced with innovative biotechnologies creates a problem for the Dutch authorities in that these events are not officially listed. Given the absence of a database with genome edited varieties, the authorities have no information on which crop and genome sequence they must sample and test. In a [letter to the Parliament](#) (Dutch language) of March 26, 2021, (former) Minister Schouten stated that the exporter is responsible for informing the importer and distributor about the use of innovative biotechnologies, including CRISPR-Cas9.

While a database with a complete list of genome edited plant varieties is absent, the [EUginus database](#) began to add information on varieties produced with innovative biotechnologies. The EUginus database is an initiative of the German Federal Office of Consumer Protection and Food Safety and the Netherlands’ [Wageningen Food Safety Research \(WFSR\)](#). The database provides detailed information on relevant issues regarding the presence, detection, and identification of “GMOs.”

#### i) Low Level Presence (LLP) Policy

The Dutch regulation for LLP is based on EU legislation. It follows the “technical solution” guidance that defines zero as an allowance of 0.1 percent, as outlined in [EU Regulation 619/2011](#). This regulation lays down the methods of sampling and analysis of official control of feed regarding the presence of GE materials for which an authorization procedure is pending or the authorization of which has expired. Besides an LLP regulation for unapproved GE varieties in feed, the Dutch Government supports a technical solution for the zero tolerance for unapproved GE events in food.

#### j) Additional Regulatory Requirements

The Netherlands implements EU legislation.

#### k) Intellectual Property Rights (IPR)

The Netherlands implements EU IPR legislation and does not have its own IPR laws that would protect patents on plant biotechnology. The main concern of the Dutch Parliament related to genetic engineering is the dominant position of the multinational seed companies in the food sector. The Dutch Government’s response is that, if needed, EU and international patent laws should be changed to assure biological material is freely available for the development of new varieties.

During the first half of 2016, the Netherlands chaired the EU Council. The imbalance between patent rights and farmer's rights was one of their priorities. The Dutch Government organized a symposium called, "[Finding the Balance](#)", during which the European Commissioner for the internal market, Elzbieta Bienkowska, provided specific interpretation of the current EU legislation, in particular with relation to the accessibility of genetic material and patentability of plant varieties. On November 3, 2016, the European Commission published a [Commission Notice](#) on certain articles of [Directive 98/44/EC](#) stating that products derived from essentially biological processes (conventional breeding) cannot be patented.

On June 8, 2023, Minister of Agriculture Piet Adema updated the Dutch Parliament on the position of the Dutch Government towards IPR of "NGTs" with a [letter](#) (Dutch language). In this letter, the Minister explained that "NGTs" can be patented through initiatives of the International Licensing Platform for vegetable varieties and, since 2023, by the Agricultural Crop Licensing Platform for field crop varieties. Furthermore, is the patenting of "NGTs" registered by the Patent Information and Transparency Online (PINTO). In the letter, he states that the patent can only be granted for a plant that is developed by patented technology and not for a similar plant that has been developed by conventional breeding methods.

#### l) Cartagena Protocol Ratification

The Netherlands is a signatory of the Protocol and it entered into force in September 2003. In the Netherlands, the VROM is responsible for the implementation of the Cartagena Protocol on Biosafety (CPB). The Netherlands has enforced the Protocol through the implementation of EU directives in the "GMO" Act.

#### m) International Treaties / Forums

The Netherlands is a member of the International Plant Protection Convention and the Codex Alimentarius. Through the National Institute for Public Health and the Environment (RIVM), the Netherlands has contributed to the work undertaken by the Organization for Economic Co-operation and Development on risk assessment and risk management. In general, the Dutch Government takes the position that the regulations related to the trade and processing of GE crops must be workable for the private industry and enforceable by the authorities.

#### n) Related Issues

No other related issues to report.

## PART C: MARKETING

#### a) Public / Private Opinions

The [Dutch Farmers Organization](#) (known as the LTO) (Dutch language) is pragmatic and in favor of innovative biotechnologies. The LTO states that farmers want to be less dependent on chemicals and

invest in robust agricultural systems, with the DNA of the plant as a basis element (see also the LTO report [Ambitions Plant Health 2030 - Dutch language](#)). The LTO argues that innovative biotechnologies are an important tool to breed resistant varieties, and must be deregulated, considering certain preconditions: the freedom of choice for the farmer (coexistence and breeders' rights) and consumer, and the enforcement of a scientific approval process to determine the safety for the environment and humans. The LTO reiterated its standpoint in reaction to the [new rules to reduce the risk and use of pesticides in the EU](#) in a [press release](#) (Dutch language) on June 22, 2022. The Dutch Arable Crop Board (NAV) stated that all techniques by which no foreign DNA is implemented (cis-genesis) should be approved. However, the NAV is not supportive of trans-genetic modification. The Dutch plant breeding and propagation sector (known as [Plantum](#) - Dutch language) is supportive of the use of innovative biotechnologies, and states that the technology must be made available for both large and small companies. The organization also states that the freedom of choice must be guaranteed for organic farmers as well as for farmers who want to use plants produced with "NGT"s. The Netherlands is one of the main producers of vegetable seeds globally.

HollandBIO is the Dutch biotechnology association, with members covering the medical, industrial, and agricultural biotechnology sector. In their [press release](#) of June 20, 2023 HollandBIO reacts generally positive towards the (leaked) EC proposal on regulating "NGTs". But the sector organization also states that the proposal appears to be seeking a political compromise in finding the criteria for classifying the "NGT" crop variety as either Category 1 or 2, as outlined in Annex I. HollandBIO is also critical towards the decision that "NGTs" which fall under Category 1 will remain "GMOs" according to the provisions of the organic sector.

## b) Market Acceptance / Studies

Because GE crop plantings are absent, and GE labeled food products are scarce, Dutch consumers are not conscious of the developments in agricultural biotechnology. Food products containing GE ingredients are not seen in the marketplace because food processors have reformulated their products to avoid the need for a "GMO" label. If GE crops were planted and GE labeled food was on the market, environmental NGOs would likely object.

The Dutch livestock sector benefits from access to feed materials produced in third countries, mainly soybean meal, which is mostly GE. There is no resistance by consumers since meat produced with GE feed does not have to be labeled. Traders estimate the European non-GE soya market at about fifteen percent of the total feed grade market, with a lower percentage for the Dutch market. The share of organic feed grade soya is estimated to be less than five percent. For more information see [The Netherlands Signs the European Soya Declaration](#), dated July 24, 2017.

On June 3, 2019, COGEM published the report "[Perceptions of citizens about genetic modification](#)" (in Dutch). The study determined, among other findings, that genetic modification evokes positive feelings and admiration for technical ingenuity for many citizens. However, serious threats, such as a concentration of control over technology and power by multinationals, unforeseen consequences, and the upsetting of nature's balance are often mentioned.

On November 30, 2022, the Dutch branch of the International Union for Conservation of Nature (IUCN), commissioned by VROM, published an inventory ([Biotechnology in a Broader Perspective](#)) of

the standpoints of the nature and environmental NGOs in the Netherlands. The overall conclusion of the report is that most of the NGOs are skeptical of the potential of biotechnology, particularly related to the benefits of improving the sustainability of agricultural and industrial systems.

## CHAPTER II: ANIMAL BIOTECHNOLOGY

### PART D: PRODUCTION AND TRADE

#### a) Product Development

In the Netherlands, there are no GE or cloned animals under development that will be on the market in the coming five years. The application of biotechnology in animal breeding for recreation and sport is prohibited but permitted for biomedical purposes. For the application in agriculture, a clear position has not yet been taken, but animal welfare is an important consideration. In the Netherlands, research conducted on animal biotechnology for application in agriculture is limited. WUR investigated the use of genome-editing for the introduction of the polled variant in cattle to stop the practice of dehorning. The [project](#) used computer simulation to determine the impact of genome editing.

As outlined in Chapter I, the Dutch Government developed the “[Top Sectors](#)” (Dutch language) policy. As a part of the policy, the Dutch Government developed an [innovation agenda](#) (Dutch language) for the application of animal biotechnology. The agenda is focused on the reduction of greenhouse gas emissions (by cows) and higher stress resistance (against, for instance, wet conditions), disease resistance, and the phasing out of lab tests on animals. Phenotyping and genotyping are mentioned as the main tools (not genome-editing). Genome editing is not listed as one of the skills mentioned by the [Livestock Research Institute](#) of the WUR. Its research is mainly focused on recording genetic properties for selection purposes and developing methods for improved genetic selection.

#### b) Commercial Production

In the Netherlands, there are no GE or cloned animals for commercial use. GE animals are only authorized for use as laboratory animals for medical research at universities and academic hospitals. Annually, 15 to 20 licenses are granted. The largest group of GE animals is mice. Neither the Dutch livestock sector nor Dutch agricultural research institutes keep GE animals (even for research purposes).

#### c) Exports

As domestic production of GE and cloned animals does not exist, the Netherlands does not export domestically produced GE or cloned animals or their reproductive materials. However, the Dutch livestock and dairy sector most likely imports and further trades semen and embryos from cloned animals.

#### d) Imports

The Netherlands has likely imported semen and embryos from cloned animals. The specific quantity of these imports is not available. There are no known imports of GE animals.



## e) Trade Barriers

The EU “GMO” legislation applies to GE animals, and although no GE animal applications have been submitted to the EU, these regulations would inhibit trade of such products. The import of cloned animals for food use requires EU pre-market approval. Currently there are no trade barriers to the offspring of cloned animals. However, future legislation could introduce barriers.

## PART E: POLICY

### a) Regulatory Framework

Currently, the Dutch Government has regulations in place for the genetic engineering of animals, but not for the practice of cloning animals. The rules are laid down in the [Animal Law](#) (Dutch language) article 2.23:

- It is prohibited to modify the genetic material of animals solely for sporting performance or entertainment in a manner that ignores the natural barriers to sexual reproduction and recombination.
- It is prohibited without a permit: (a) to modify the genetic material of animals in a manner that bypasses the natural barriers to sexual reproduction and recombination; (b) apply biotechnological techniques to an animal or an animal embryo.

Organizations which want to use GE animals for medical research need to request a license from the Dutch Ministry of Agriculture, Nature, and Food Quality (MinAg). Licenses are granted only if the genetic engineering has acceptable outcomes for the animal’s health and welfare, and there are no ethical objections to the proposed application. The Committee on Animal Biotechnology assesses all incoming license requests. The rules for biotechnology application requests are laid down in the Animal Biotechnology Decree and enforced by the NVWA.

In addition to a license granted by the MinAg, institutes or corporations wanting to make, reproduce, keep, or transport GE animals also need a license from the Minister of Infrastructure and the Environment, who assesses the project’s potential adverse effects on humans and the environment. This requirement is based on the Decree on “GMOs”.

The Dutch Government does not oppose the European Commission (EC) proposal to ban food from clones, but only if the regulation is practical and in line with international obligations. The Dutch Government has not decided about whether the prospective EU ban on products from clones should also include products of the progeny of clones. The position of the current Dutch caretaker coalition Government is not yet known, and it is unclear if the topic will be on the political agenda.

On June 14, 2016, COGEM published a report: [Trendanalyse Biotechnologie 2016, Regelgeving Ontregeld](#) (Trend Analysis Biotechnology 2016, Regulations Deregulate – in Dutch). In a [letter](#) (in Dutch), the (former) State Secretary of Health Sharon Dijksma presented the report to the Parliament

and specifically referred to the risks of GE organisms with *gene drives*, as described in Science, Augustus 28 2015, Vol. 349, no. 6251, pp. 927-929. With *gene drives*, the GE organisms will solely produce GE offspring. The State Secretary concluded in the letter that the government will include the risks of *gene drives* in the assessment of the incoming license requests, and, in addition, will call for international measures. On April 4, 2019, the State Secretary informed the Parliament that the “GMO” Regulation has been amended, by which the Ministry of Infrastructure and Water Management (VROM) decreed that permits be requested for all applications using *gene drives*. The rules for the [risk assessment](#) (Dutch language, English summary) were published by the National Institute for Public Health and the Environment (RIVM).

The Dutch Government contracted Bureau Berenschot to evaluate the Dutch Animal Law. On July 8, 2020, the concluding report [Evaluatie van de Wet Dieren](#) (Dutch language) was published. The report states that animal welfare issues are covered by EU legislation, but that EU rules for the application of biotechnology for animal breeding are almost non-existent.

#### b) Approvals

The Netherlands implements EU legislation and does not have its own approval procedures for GE animals or cloning. For more information see the [Agricultural Biotechnology Annual - European Union](#).

#### c) Innovative Biotechnologies

The Netherlands has not yet decided how to regulate innovative biotechnologies in animals. The Netherlands implements EU legislation. For more information see the [Agricultural Biotechnology Annual - European Union](#).

#### d) Labeling and Traceability

The Netherlands implements current EU legislation. As part of or in addition to EU legislation, the Dutch Government wants to implement a traceability scheme for reproductive material. For more information see the [Agricultural Biotechnology Annual - European Union](#).

#### e) Intellectual Property Rights (IPR)

The Netherlands implements EU legislation and does not have its own IPR laws that would protect patents on animal biotechnology. For more information see the [Agricultural Biotechnology Annual - European Union](#).

#### f) International Treaties / Forums

The Netherlands is a member of Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE). However, the Netherlands does not take an active position regarding animal biotechnology in these organizations.

#### g) Related Issues

No other related issues to report.

## PART F: MARKETING

### **Animal Biotechnology Marketing**

#### a) Public/Private Opinions

Government and livestock sector representatives are, in general, educated on the subject, but are not supportive of cloning and GE animals. Their policy is based on the public's aversion to the technique. Dutch citizens and consumers do not support the use of cloning and/or genetic engineering technologies by the livestock sector.

Between March 2021 and February 2022, the Rathenau Institute organized six seminars to consult the Dutch public about their viewpoint on the use of animals as organ donors. The main conclusion of the report: "[The Animal as Donor](#)" (Dutch language) was that Dutch citizens take ethical considerations into account in the application of animal donors. The main recommendation in the report for the Dutch Government was to continue to support the availability of animal-free donor options.

#### b) Market Acceptance / Studies

So far, authorization of GE animals is limited to the use for medical research by universities and academic hospitals. The research project, [Social Aspects of Genome Editing in Animals](#), conducted by WUR and Utrecht University, is developing a comparative innovation approach to examine the conditions, if any, under which genome editing should be applied to animal breeding applications. On August 31, 2021, the group published the report: [Gene editing of livestock: Sociotechnical imaginaries of scientists and breeding companies in the Netherlands](#). In the report, the researchers concluded that livestock gene editing raises more concerns and questions from the Dutch public than the applications in plants. The researchers state that the different interpretation is possibly a response to the major controversies that occurred when GE crops arrived in Europe and based on the animal welfare dilemmas in the intensive livestock sector.

Besides the public's aversion, the lack of confidence of Dutch scientists in the potential of the technology is a limiting factor of the commercial uptake of technology. In the new [Trend Analysis Biotechnology 2023](#), published on April 20, 2023, COGEM outlines that the Dutch universities and the livestock sector are hesitant towards the application of gene editing in animals due to the technical barriers. COGEM states that the limited number of monogenes (a single gene involved in the expression of a trait), and the time needed for crossbreeding as the main barriers for the uptake of the technology.

## CHAPTER III: MICROBIAL BIOTECHNOLOGY

### PART G: PRODUCTION AND TRADE

#### a) Commercial Production

As noted, the Netherlands is home to a relatively large processing sector, converting agricultural imports into food, feed, and fuels. Microbial biotechnology is an important component of the conversion processes applied by the sector. One of the most active Dutch companies applying microbial genome editing is [DSM Food Specialties](#). The company produces food ingredients based on fermentation processes, such as nutraceuticals, yeast extracts, and vitamins. The [database](#) (Dutch language) of the National Institute for Public Health and the Environment (RIVM) reports that since 1994, DSM Food Specialties received 28 licenses for the contained use of GE micro-organisms (five since 2010). This company studies the production of lab-grown meat and meat products. Other Dutch companies applying genome editing techniques on microbes are [Isobionics](#) (microbial biotech-derived flavors) and [Veramaris](#) (biotech-derived omega-3 fatty acids).

In the Netherlands, research institutions and companies producing meat and dairy replacers have united in the [Cellular Agriculture Netherlands Foundation \(CANS\)](#) to promote cellular agriculture. Examples of Dutch companies which apply cellular agriculture are [The Protein Brewery](#) (producing Fermotein<sup>®</sup>, an alternative for vegetable and animal proteins), the [Fooditive Group](#) (producing a non-animal casein with GE yeast), [Those Vegan Boys](#) (producing vegan cheese with fungi and yeasts), [Meatable](#) (producing meat replacers and also listed in the RIVM database), and [Mosa Meat](#) (producing a lab-grown burger). For more information about the cellular agriculture sector in the Netherlands Chapter 4.3 of the report [Trend Analysis Biotechnology 2023](#), published April 20, 2023.

As outlined in Chapter I, the Dutch Government developed the “[Top Sectors](#)” (Dutch language) policy. As a part of the policy, the Dutch Government developed an [innovation agenda](#) (Dutch language) for “white” biotechnology. The agenda is focused on the conversion of waste streams, production of food and non-food ingredients, and the production of meat replacers. Genome-editing is mentioned as one of the tools to reach these goals. The main trend is the application of microbial biotechnology as a conversion technology in the [biobased economy](#) (Dutch language), for the production of biofuels, biochemicals, and biomaterials. An example is the conversion of ligno-cellulose into bioethanol by [DSM Advanced Biofuels in cooperation with POET](#). In the Netherlands, two of the leading institutes in the field of industrial biotechnology is the Delft University of Technology’s [Faculty of Applied Science](#), and the [Bacterial Genetics group](#) in the Laboratory of Microbiology at WUR. An example of the research conducted by the Delft University is the use of CRISPR-Cas technology for the [development of yeasts which grow without oxygen](#). The Dutch Government [funds](#) (Dutch language) cellular agriculture with €60 million through the [National Growth Fund](#). The funding will be allocated for research, commercialization, and education of qualified personnel.

#### b) Exports

The Dutch biotechnology sector may be exporting GE microbes, specifically yeasts. As no harmonized code exists for the GE yeast variant, the quantity or value cannot be determined. However, the Netherlands was ranked as the seventeenth largest global exporter of yeasts (HS code 2102), with a

value of \$43.5 million in 2022. After Denmark and the United States, the Netherlands is the third largest exporter of enzymes (HS code 350790) with a value of \$911 million in 2022. The United States is the main export destination outside the EU, with a value of \$98 million in 2022. DSM Nutritional Products is one of the main food ingredient producers in the Netherlands. The company received Generally Recognized As Safe (GRAS) recognition for several ingredients, including [steviol glycosides, as a sweetener](#), and [phytase enzymes, as a feed ingredient](#).

#### c) Imports

The Dutch processing sector possibly imports GE microbes. As no harmonized code exists for the GE variant, the quantity or value cannot be determined. After the United States, the Netherlands is the second largest importer of enzymes (HS code 350790) with a value of \$737 million in 2022. The leading non-EU suppliers to the Netherlands are the United States (\$74.5 million) and China (\$9.7 million) in 2022.

#### d) Trade Barriers

The Netherlands implements EU legislation. For more information see the [Agricultural Biotechnology Annual - European Union](#).

## PART H: POLICY

#### a) Regulatory Framework

The Netherlands implements EU legislation in its [national laws](#) (Dutch language). Three Ministries are responsible for the implementation and enforcement of the regulatory framework for microbial biotechnology: the Ministry of Health, Welfare and Sport (VWS), the Ministry of Infrastructure and Water Management (VROM), and the Ministry of Agriculture, Nature, and Food Quality (MinAg). Food ingredients produced with GE microbes that are new to market must comply with the EU [Novel Food](#) regulations. [Commission Implementing Regulation 2018/456](#) lists the procedural steps that food business operators must follow to consult with the competent authority of the EU Member State where they first intend to market their product. The competent authority in the Netherlands is the VWS.

Currently, cell-cultured meat is an unauthorized novel food whose safety has not been assessed under the European Novel Foods regulation. On July 5, 2023, the Dutch Government, CANS, and HollandBIO agreed upon a [Code of Practice](#), which provides a technically harmonized framework so producers, from their own responsibility, can carry out the tastings in controlled environments. For more information see the [Novel Foods page of the EC](#), the [Novel Foods page of the U.S. Mission to the EU](#), the [Food and Agricultural Import Regulations and Standards \(FAIRS\) reports of the EU and EU Member States](#), and the [Agricultural Biotechnology Annual - European Union](#).

#### b) Approvals

The [Dutch approval procedure](#) (Dutch language) follows EU Directive 2001/18/EC and Regulation 1829/2003/EC. For the contained use of GE microbes, a license from the National Institute for Public

Health and the Environment (RIVM) is necessary. The approved GE microbes are listed in the [RIVM database](#) (Dutch language). For the marketing of food additives, aromas, and enzymes at the Dutch market the [existing provisions](#) (in Dutch) will continue to apply until the adoption of an EU positive list of authorized enzymes (which is currently being worked on). Consultation requests should be sent electronically to the novel food assessment body:

Medicines Evaluation Board (CBG-MEB)  
Novel Food Unit  
P.O. Box 8275 3503 RG Utrecht, the Netherlands  
Email: [novelfoods@cbg-meb.nl](mailto:novelfoods@cbg-meb.nl)  
Website: <https://english.cbg-meb.nl/>

At the EU level, guidance documents on the use of additives, enzymes, flavorings, and extraction solvents can be found on the EC's website for [Food Improvements Agents](#). For more information see the [Agricultural Biotechnology Annual - European Union](#).

On June 26, 2023, the VROM, presented the report "[Biotechnology and Safety](#)" (Dutch language) to the Dutch Parliament. The report lists the safety considerations for several applications of "NGTs", of which in the application of industrial fungi. Dutch scientists note that the that the stringency of the approval process should be proportional to the risk of the applications, which is currently not the case.

#### c) Labeling and Traceability

The Netherlands implemented EU legislation on labeling and traceability in the [Dutch Food Law](#) (Dutch language). Products containing 0.9 percent or more GE content, per ingredient, must be labeled as a product of biotechnology. Products without GE ingredients can be labeled as "produced without gene technology" (in Dutch: bereid zonder gentechniek) if the product complies with the [Novel Foods Food Law Decision](#) (Dutch language). For more information see the [Food and Agricultural Import Regulations and Standards \(FAIRS\) reports of the EU and EU Member States](#) and the [Agricultural Biotechnology Annual - European Union](#).

#### d) Monitoring and Testing

The NVWA is actively testing feed and food imports for the presence of GE materials. The Dutch regulations for labeling, sampling, and testing are based on EU legislation.

#### e) Additional Regulatory Requirements

There are no additional regulatory requirements for microbial biotechnology in the Netherlands.

#### f) Intellectual Property Rights (IPR)

The Netherlands implements EU legislation and does not have its own IPR laws that would protect patents on microbial biotechnology. For more information see the [Agricultural Biotechnology Annual - European Union](#).

g) Related Issues

No other related issues to report.

**PART I: MARKETING**

a) Public / Private Opinions

On June 3, 2019, COGEM published the report “[Perceptions of citizens about genetic modification](#)” (in Dutch). The study determined, among other findings, that most of the Dutch respondents associated genetic modification with plants, followed by animals and humans. Microorganisms are rarely mentioned.

b) Market Acceptance / Studies

No other related studies to report.

**Attachments:**

No Attachments