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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. The main development is that the Dutch Ministry of Agriculture, Nature, and Food Quality supports the EC conclusions that innovative biotechnologies can play an important role in greening food production and a revision is needed to make the regulations future proof and fit for purpose. However, the Ministry also emphasized, when expressing it support for revised regulations, the importance of considering food safety, ethical and societal concerns, transparency, and the freedom of choice of the farmer and consumer during development. In the innovation agenda of the Dutch "Top Sector" policy, genome editing is identified as one of the key technologies that may be utilized to improve plant pest resistance and more.

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.

On July 25, 2018, the European Court of Justice (ECJ) issued a verdict in Directive 2001/18/EC to legislate innovative biotechnologies (in the EU referenced as new breeding techniques, also known as genome editing) similar to transgenic engineering. This is expected to have negative implications for Dutch agricultural sector, related trade, and the Dutch processing sector. 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[1] by 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 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. The Dutch Ministry of Agriculture, Nature, and Food Quality supports the EC conclusions that innovative biotechnologies can play an important role in greening food production and a revision is needed to make the regulations future proof and fit for purpose. However, the Ministry also emphasized, when expressing it support for revised regulations, the importance of considering food safety, ethical and societal concerns, transparency, and the freedom of choice of the farmer and consumer during development.

The Dutch livestock sector does not utilize any GE animals nor do Dutch agricultural research institutes keep them for research purposes. The Ministry of Agriculture, Nature and Food Quality has stated that the Dutch Government does not oppose the European Commission's 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. As a consequence, 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 replacers. Genome-editing is mentioned as one of the tools that could be utilized to reach these goals.

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

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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 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 (RIVM) reports that in 2019 and 2020 only one license was granted for market introduction (listed as MA in the database) of a GE plant. 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 for the production of 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 for field trials (for more information see PART B: POLICY / d) Field Testing.

The Wageningen University's (WUR) Research Group on Ornamentals, Tissue Culture and Gene Technology, focuses on developing and implementing the latest plant breeding techniques in ornamental plants. For food products, such as grains, WUR reviewed the application of gene editing of gluten in wheat to reduce gluten content. The scientists concluded that the application of gene editing offers the prospect of producing hypoimmunogenic wheat but that probably several approaches must be combined. For additional information, see https://www.wur.nl/nl/Publicatie-details.htm?publicationId=publication-way-353634303530.

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. The Ministry'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.

Imports of Soybeans and Meal, the Netherlands (1,000 MT)						
	2015	**2016**	**2017**	**2018**	**2019**	**2020**
Soybeans	4,378	4,687	3,847	4,280	4,115	4,537
-United States	1,792	2,136	1,888	3,030	1,594	1,582
-Brazil	1,273	1,692	1,140	991	1,799	2,344
Soybean meal	4,009	3,140	3,081	2,724	2,678	2,579
-Brazil	2,558	2,029	2,127	2,044	1,950	1,826
-Argentina	1,046	809	660	321	269	319

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). On August 17, 2021, the EC approved seven GE crops (three corn, two soybean, one rapeseed, and one cotton) and renewed the authorizations for two corn and one rapeseed crop used for food and animal feed. For more information see GAIN Report - European Commission Authorizes 10 GE Crops for Import.

Due to the tight supply of non-GE and organic soybeans, the Dutch Government signed the European Soya Declaration, which supports European soybean production. Soy traders and feed compounders report a price premium of €50-100 per metric ton (MT) for non-GE feed grade and €100-150 per MT for non-GE food grade soybeans. For more information, see 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 Ministry of Agriculture, Nature and Food Quality 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 Dutch Ministry of Agriculture Launches National Protein Strategy, dated January 19, 2021.

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 the 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)

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 the area of food.

The Ministry of Infrastructure and Water Management (MIW) - 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 (LNV) - Responsible for GE legislation in the feed and seed area. Together with VWS, LNV plays an important role in the implementation of the EU Traceability and Labeling legislation. LNV 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 based on 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 2017 did not result in a single 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). The VVD, D66 and CDA are generally supportive of agricultural biotechnology, although D66 is a strong supporter of labeling and has expressed concerns about the Dutch "dependency" on GE soya imports. More recent elections were held in March 2021, but, as of the date of this report, a new government coalition has yet to be formed. Accordingly, the coalition developed from the 2017 elections remains in power in "caretaker" status.

The election programs of the VVD, D66, and CDA political parties (all Dutch language) express the parties' support for modernizing the EC regulations leading the way to apply innovative biotechnologies in the agricultural and horticultural sector. In the election programs (all Dutch language) of the Green Party (Groenlinks), Labor Party (PvdA), and CU innovative biotechnologies are not mentioned, but the party's keywords are respectively, organic, sustainable, and circular. The concept election program of D66 (Dutch language) for the last Parliamentary elections (March 2021), indicated that the party accepts the scientific consensus that crops produced with genetic engineering are as safe as produced with classical plant breeding methods. The program further stated that the EU regulations must be modernized to support the application of innovative plant biotechnologies (such as CRISPR-Cas). The CU has ethical concerns related to the application of innovative breeding technologies, except for cis-genesis (transfer of genes within the species), which they support. NOTE: In the Coalition Accord (Dutch language – the Accord) of November 10, 2017, the Dutch Cabinet (now in "caretaker" status) stated that the Netherlands will support the application and approval of innovative biotechnologies, such as CRISPR-Cas9, if no genes are transferred between species (trans-genesis). Furthermore, the Accord supports innovation in the agricultural sector in order to improve the sustainability of agricultural production, specifically for water usage and food security.

Carola Schouten, the current Minister of Agriculture, Nature and Food Quality, has also put forward the Ministry's vision for the Dutch agricultural sector towards 2030. The main theme, and goal, of this

vision is circular agriculture (known in Dutch as "kringlooplandbouw"). A detailed plan (Dutch language) and agenda (in Dutch) for putting this vision in practice was published on June 17, 2019. In the documents, the Minister stated that she will pursue to actualize the current EU genetically modified organism ("GMO") legislation so that the application of innovative biotechnologies will not be restricted. She further states that genome editing is one of the main innovation drivers for agriculture and has potential for use in circular agriculture. 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.

On May 20, 2020, the EC announced both the Farm to Fork (F2F) and the Biodiversity Strategies as roadmaps for enhancing food and agricultural sustainability by 2030 under the EU's Green Deal. The strategy targets a fifty percent reduction in pesticide use. On June 26, 2020, Minister Schouten informed the Dutch Parliament that the Dutch approach to reach the goals set by the F2F strategy is through the circular agriculture model with robust crop culture systems, less dependence on pesticides and the safe use of biotechnology.

In the State Budget of the Netherlands for 2022, made public on September 21, 2021, section XIV – Agriculture, Nature and Food Quality (Dutch language) the Dutch Cabinet identified five key technologies for agriculture, which included biotechnology and plant breeding. The policy document further refers to a request of the Dutch Parliament to cooperate with like-minded countries (particularly Germany, Spain, Denmark, Estonia, and Sweden) to increase support for the revision of the EU regulations related to biotechnology and plant breeding.

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 11, 2014, however, the Dutch Government cast its first ever negative vote for a biotech dossier at the EU Council (Pioneer 1507 maize for cultivation). While the Dutch Cabinet opposed this change in position, the decision was the result of a direct instruction from the Parliament.

For more information see the Agricultural Biotechnology Annual - European Union.

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. Despite this resistance, in 2013, Wageningen University started a trial with a potato variety which is resistant against phytophthora (late blight). The potato is made resistant by transferring genes from another resistant potato (cis-genesis). A license was also granted for an ongoing

field trial with apples. The apples are made resistance against apple scab through cis-genesis. The market introduction of the potato and apple variety is not expected within the next five years. 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

The application of innovative biotechnologies in agriculture has the attention and support of the Dutch Government. This support 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. The current policy position of the government allows for products produced with innovative biotechnologies, as long as they are deemed to be as safe as conventional breeding. In order to determine if the technology produces safe food, the Dutch Government consults the studies of the European Food Safety Agency (EFSA), the Institute of Food Safety of the Wageningen University (RIKILT), and the National Institute for Public Health and the Environment (RIVM). The Dutch Government has also determined that plant products produced through cis-genesis are as safe as products produced with conventional breeding, and that products of cis-genesis should be exempted from the legislation for GE products, EU Directive 2001/18/EC.

On September 7, 2017, the Dutch Government presented a proposal to the European Commission and EU Member States on how products derived from innovative biotechnologies could be regulated. The proposal holds the view that plants resulting from "NBTs," provided that 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. Therefore, "NBTs" should fall under Annex IB of the Directive. This proposal was not intended to rewrite the Directive, but to update Annex IB. It further recommends not listing all possible exempted techniques on a case-by-case basis, as was done in the past, but, rather, to set forth criteria in Annex IB that would be based on the final product rather than the technique used to develop it. For more information see FAS GAIN Report Dutch Proposal to Legislate NBTs, dated September 29, 2017.

On July 25, 2018, the European Court of Justice (ECJ) issued its judgment that organisms created through non-conventional mutagenesis are to be regulated as GE varieties, following Directive 2001/18/EC. The ECJ verdict is based on the precautionary principle and indicates that other innovative biotechnologies will have to comply with the risk assessment and labeling conditions laid down in the Directive. The Directive imposes expensive and lengthy approval processes as well as traceability, labelling, and monitoring obligations for GE crops. For more information on the details of this directive, see EU Court Extends GMO Directive to New Plant Breeding Techniques, dated July 27, 2018.

The ECJ's verdict to legislate innovative biotechnologies as a trans-genetic modification is expected to have significant negative implications for the Dutch agricultural and horticultural sector. Not only will the competitiveness of the domestic seed, crop, and livestock sector be affected, but it will also have a negative impact on Dutch trade and processing sector. If soybean varieties developed with these innovative plant breeding methods will be commercialized, the enforcement of this decision could

possibly curtail the import of soybeans and soybean meal (a crucial input for the intensive European livestock sector).

On November 30, 2018, three ministries of the Dutch Government (Ministry of Infrastructure and Water Management, Ministry of Agriculture, Nature and Food Quality, and the Ministry of Health, Welfare and Sport) informed the Dutch Parliament about their conclusions regarding the decision of ECJ. Their letter (Dutch language) to the Dutch Parliament stated that the verdict does not provide sufficient clarification on which innovative biotechnologies should fall under the "GMO" Directive 2001/18/EC and which should not. As a result, the Dutch Government plans to call for an amendment of the EU Directive in line with their earlier proposal that plants resulting from innovative biotechnologies should be exempt from the "GMO" Directive provided they are at least equally safe as plants obtained through traditional breeding. In the long term, the Dutch Government will call for broader modernization of the EU biotech legislation. For more information see The Netherlands Calls for an Amendment of the "GMO" Directive, dated December 10, 2018.

On March 21, 2019, the Netherlands Commission on Genetic Modification (COGEM) supported the position of the Dutch Government with their Advice (in Dutch) to the Dutch Ministry of Infrastructure and Environment. The Advice includes a proposal for the textual change of the Annex IB of Directive 2001/18/EC language:

1) No genetic material is introduced into the resulting plant other than genetic material from the same plant species or from a plant species with which it can exchange genetic material through traditional breeding methods.
2) Recombinant nucleic acid molecules that are used for or during modification are no longer present in the resulting plant that is meant for deliberate introduction into the environment.

On May 14, 2019, the Dutch Government, with support of the Estonian delegation, put a Note with the subject "*Follow up to the judgment of the Court of Justice in Case C-528/16*" on the May agenda of the Agricultural and Fisheries (AgriFish) Committee of the EU Council. The Note states that biotechnology has progressed and, although the ECJ provided more legal clarity, a review of the adequacy of the current EU legislation for GE crops and products is required. Fourteen EU Member States supported the proposal to address the complications related to the current legal status of innovative biotechnologies. In the Council press release is was also stated that: "{t}he request of a common EU approach was supported by many delegations that generally asked for a consistent interpretation and an update of the current "GMO" legislation."

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 - European Commission Publishes Biotechnology Study, published May 21, 2021, as well as an EC presentation from the 12th Meeting of the Network of Risk Assessment of GMO on June 10, 2021.

In three letters by Minister Schouten to the Dutch Parliament, Minister Schouten stated that she supports the EC conclusions that innovative biotechnologies can play an important role in greening food production and that the current GMO legislation is out of date. She also concurs with the EC that a revision is needed to make the current regulations future proof and fit for purpose. However, the Minister also emphasized, when expressing support for revised regulations, the importance of considering food safety, ethical and societal concerns, transparency, and the freedom of choice of the farmer and consumer during development. For more information see the letters to Dutch Parliament of May 12, June 4, and June 14, 2021 (all Dutch language).

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 the FAS GAIN Report - European Commission Publishes Roadmap on Legislative Initiative for Plants Produced by Certain Genome Editing Techniques, published October 1, 2021.

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 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. Legislative options for innovative biotechnologies were also discussed by the Dutch Rathenau Institute. One of the options mentioned in their report is the Norwegian model, which is a two-tier model based on the genetic changes and the societal values of the product. The Norwegian model is also discussed in an article published in "Plants People Planet (PPP)," drafted by WUR and Rathenau Institute researchers. In the article the researchers conclude that the application of the Norwegian level-based regulatory framework can help move the focus away from assessments on safety to a tiered assessment of socio-economic considerations.

Dutch Government support for research on innovative biotechnologies
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 technologies 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 for the production of 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. In 2018 the Commission proposed an ambitious €100 billion research and innovation program - Horizon Europe - to succeed Horizon 2020. The EU institutions set the budget for Horizon Europe at €95.5 billion.

f) Coexistence

In 2004, the Dutch agricultural sector and environmental NGOs agreed on coexistence regulations which were accepted by the Dutch Ministry of Agriculture, Nature, and Food Quality. The Product Board for Arable Crops was responsible for the implementation of the regulations. However, with the abolishment of this organization, the national coexistence regulation was transposed to a government regulation as of January 1, 2015. 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, Minister Schouten replied to concerns outlined by the Christian Democratic Party (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) of October 7, 2020, Minister Schouten added that transparency and the "freedom of choice" are important for the organic as well as the conventional sector. 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 Netherlands Food and Consumer Product Safety Authority (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, 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 EUginius database began to add information on varieties produced with innovative biotechnologies. The EUginius 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 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. In the Coalition Accord of the current Dutch Cabinet it states that the Netherlands will support breeder's rights, meaning that farmers should be able to use their farm-saved seeds for planting and for crossbreeding.

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 September 6, 2021, WUR provided free licenses to non-profit organizations to use its CRISPR–Cas gene-editing technology for non-commercial applications So that CRISPR tools can be used, for instance, to help make food production sustainable, nutritious, and safe. The university hopes that the move will inspire a worldwide change in CRISPR–Cas intellectual-property policy.

l) Cartagena Protocol Ratification

The Netherlands is a signatory of the Protocol and it entered into force in September 2003. In the Netherlands, the Ministry of Infrastructure and Water Management (MIW) 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, taking into account 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 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. The Netherlands is one of the

main producers of vegetable seeds globally. This sector also believes biological material, protected by patent rights, should be freely available for the development of new varieties.

HollandBIO is the Dutch biotechnology association, with members covering the medical, industrial, and agricultural biotechnology sector. Recently HollandBIO commented on the Inception Impact Assessment of the EC. HollandBIO stated that:

> Overall, the contours of the proposed future policy seem to be no different than the policy aims that led to the current GMO legislation, besides the addition of sustainability requirements. Without a clear paradigm shift, from technology based towards product-based regulation, the current deadlock will prevail. It is unclear to us how this roadmap will break the status quo and result in balanced, future-proof regulation, establishing a global level playing field for innovation, enabling European biotechnology to make life better.

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. Fewer respondents hold negative feelings about and fundamental objections to genetic modification. 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.

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).

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. 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. 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 rules for biotechnology application requests are laid down in the Animal Biotechnology Decree which are enforced by the Netherlands Food and Consumer Product Safety Authority (NVWA).

In addition to a license granted by the Minister of Agriculture, 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".

In a letter (in Dutch) to the Dutch Parliament, dated November 30, 2015, the former Minister of Agriculture stated that the Dutch Government supports the temporary EU-wide ban on cloning of farm animals. The Cabinet does not oppose the European Commission 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 four-party 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 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 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. These practices are also not accepted by the majority of Dutch livestock and dairy farmers, breeders, and several leading Dutch researchers.

On July 17, 2019, the Rathenau Institute published the report: "Essentially Different" (Dutch language). The report discusses the use of combined animal and human genetic material for medical purposes. This practice is not yet regulated in the Netherlands. One of the main conclusions of the study is that the Dutch public opinion on the technology depends on its purpose. The institute advises to periodically monitor the progress of the technology and the fast-changing public opinion.

On November 7, 2017, the Ministry of Infrastructure and the Environment published the report: The Citizen Speaks, citizen opinions about modern biotechnology (Dutch language). The report concludes that the generic term biotechnology is deemed vague by the public. Most Dutch citizens support the use of modern biotechnology for the breeding of plants but have a negative view of the application for the breeding of animals.

b) Market Acceptance / Studies

Generally, the public is not supportive of cloning or GE animals, and so the market reflects this position. So far, authorization of GE animals is limited to the use for medical research by universities and academic hospitals. Within Dutch society and the government, there is no consensus on what is ethically acceptable if such technologies are applied in the medical sector. Therefore, the Committee on Animal Biotechnology assesses all incoming license requests. Assessments are made on a case-by-case basis, but, eventually, clear guidelines on what is or is not ethically acceptable in research involving cloning or genetic engineering of animals will need to be developed.

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.

CHAPTER III: MICROBIAL BIOTECHNOLOGY

PART G: PRODUCTION AND TRADE

a) Commercial Production

Due to its geographical location and infrastructure, the Netherlands is the gateway to Northwestern Europe. As a consequence, the Netherlands has also 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). Another food company listed in the RIVM database is Meatable. 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), Veramaris (biotech-derived omega-3 fatty acids), and Photanol (converting CO_2 in renewable chemicals by cyanobacteria). Currently, Photanol is conducting contained field trials with cyanobacteria.

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, bio-chemicals, 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.

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 sixteenth largest exporter in the world of yeasts (HS code 2102), with a value of $52.5 million, in 2020. After Denmark, and ahead of the United States, the Netherlands is the second largest exporter of enzymes (HS code 350790) with a value of $730 million in 2020. The United States is the main export destination, with a value of $84.2 million in 2020. 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 $541 million in 2020. The main non-EU suppliers to the Netherlands are the United States ($61.9 million) and China ($8.9 million) in 2020.

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 (MIW), and the Ministry of Agriculture, Nature and Food Quality (LNV).

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 Ministry of Public Health, Welfare, and Sport.

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). In addition, there are restrictions (food law in Dutch) on the use of enzymes in meal and bread in the Netherlands. According this food law the only enzymes permitted are glucose-oxidase, lipase, and asparaginase of Aspergillus niger. In the Netherlands, the competent authority is the Ministry of Public Health, Welfare and Sport. 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
> 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.

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 Netherlands Food and Consumer Product Safety Authority (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