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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 and animal biotechnologies. The main development is that on May 14, 2019, the Dutch Government called for a review of the adequacy of the current EU legislation to cover the rapidly progressing technical developments in the plant breeding sector.

SECTION I: 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. The majority of the soybeans are imported from the United States. However, domestic crop trials and commercial cultivation of GE crops are effectively prevented by cumbersome regulations and the threat of protests from environmental groups.

Innovative plant biotechnology is a subject which has the strong attention of the Dutch Government, based on its potential for the Dutch plant breeding sector and for improving the sustainability of agricultural production. In the Coalition Accord of November 10, 2017, the Dutch Cabinet stated that the Netherlands will continue to support the approval and application of innovative plant biotechnologies if no genes are transferred between species (trans-genesis).

On July 25, 2018, the European Court of Justice (ECJ) issued a verdict to legislate innovative biotechnologies similar to transgenic engineering in Directive 2001/18/EC. This is expected to have negative implications for Dutch agriculture, related trade, and the Dutch processing sector. In a letter sent to the Dutch Parliament on September 17, 2018, the Dutch Minister of Agriculture, Carola Schouten, stated that stricter EU legislation for innovative biotechnologies could lead to a competitive disadvantage for the Dutch agricultural sector.

On November 30, 2018, three ministries of the Dutch Government, covering environment, health and agriculture, informed the Dutch Parliament that the ECJ verdict does not provide sufficient clarification on which innovative biotechnologies should fall under the genetically modified organism (GMO) Directive 2001/18/EC and which should not. The ministries further stated that the Dutch Government plans to call for an amendment of the EU legislation to identify which 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). This approach is in line with an earlier proposal presented by the Dutch Government to the European Commission on September 7, 2017.

On May 14, 2019, the Dutch Government, with the support of the Estonian Government, put a Note on the agenda of the Agricultural and Fisheries Committee of the EU Council. The Note states, given innovative technological developments, a review of the adequacy of the current EU legislation for GE crops and products is required. Reportedly fourteen EU Member States supported the request to evaluate the current EU legislation for GE crops.

The livestock sector does not utilize any GE animals nor do Dutch agricultural research institutes have 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.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

CHAPTER I: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) Product Development

The Netherlands has 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. For example, Wageningen University conducts research on cis-genic potatoes and apples. 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 2018 and 2019 only one license was granted related to plant breeding. The license was requested by a Japanese breeder to market a genetically engineered 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.

1) 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.

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. On March 11, 2015, Directive (EU) 2015/412 was officially released (for more information see the FAS GAIN Report SP1743 – *EU Agricultural Biotechnology Annual*, dated December 22, 2017). Regarding this "opt-out" of cultivation option, the Dutch Government will determine if they will allow

cultivation per-GE-crop. This judgment will be made by the Ministry of Agriculture, Nature and Food Quality based on a scientific assessment framework and in consultation with a commission. The Dutch Rathenau Institute organized a stakeholder's dialogue about 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.

2) 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 the EU legislation.

3) 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 the second largest soybean and soybean meal importer in the world. Soybeans and derivatives are imported from the United States and Brazil and soybean meal from Brazil and Argentina (see table below). The share of these shipments which contain GE material is not registered, but estimated to be over 85 percent.

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 mt for non-GE feed grade and €100-150 per mt for non-GE food grade soybeans. For more information see the FAS GAIN Report NL7021 - *The Netherlands Signs the European Soya Declaration*, dated July 24, 2017.

Imports of Soybeans and Meal, the Netherlands (1,000 mt)					
	2014	**2015**	**2016**	**2017**	**2018**
Soybeans	3,070	4,378	4,687	3,847	4,280
-United States	1,124	1,792	2,136	1,888	3,030
-Brazil	1,420	1,273	1,692	1,140	991
Soybean meal	4,670	4,009	3,115	3,064	2,705
-Brazil	2,720	2,558	2,029	2,127	2,044
-Argentina	1,383	1,046	809	660	321

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. In the letter, 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 relates to the cultivation of crops in other countries. Given the importance of international trade for the Dutch economy, this Dutch Government's position on this subject is not likely to change.

4) 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).

5) Trade Barriers

The *slow approval process* for new GE events and unpractical EU regulations for the allowed *Low-Level Presence* (LLP) of GE materials in shipments by the European Union 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 caused processors to avoid using products of GE crops varieties. This affected the sourcing of vegetable oils, which 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 regarding agricultural biotechnology. The following three Ministries are responsible for implementation and enforcement of the regulatory framework for agricultural biotechnology:

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 the Environment (MIE) - 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 main factor 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 input 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. 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. In the Coalition Accord of November 10, 2017, the Dutch Cabinet 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.

The Dutch Minister of Agriculture, Nature and Food Quality, Carola Schouten, of the CU has recently put forward the Ministry's vision for the Dutch agricultural sector towards 2030. The main theme, and goal, of this vision is circular agriculture ("kringlooplandbouw"). A detailed plan and agenda (in Dutch) for putting this vision in practice was published on June 17, 2019. In the documents, the Minister states that she will pursue to actualize the current EU "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. Earlier, in the Plant Protection Vision for 2030 (in Dutch), it was stated that gene editing is a fast technique to improve the disease resistance of plant species.

b) Approvals

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.

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 resistant against apple scab through cis-genesis. Environmental NGOs have sued the experiments but both trials are still taking place. The market introduction of the potato and apple variety is not expected within the next five years. Information about the field trials can be found at the website of the Bureau for Genetically Modified Organisms (BGGO).

e) Innovative Biotechnologies

The application of innovative biotechnologies in agriculture has the keen 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 genetically engineered (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 "new breeding technologies" (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 NL7030 – 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 the FAS GAIN Report E18052 - 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 competiveness 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. Soybean meal is a crucial input for the intensive European livestock sector.

Two Dutch Parliament Members of the Liberal Party (VVD) sent a letter with questions to the Dutch Minister of Agriculture, Carola Schouten, regarding the ECJ verdict. The letter asks the Minister if she is willing to encourage the modernization the current EU legislation or the drafting of new legislation. On September 17, 2018, the Minister replied with a letter (Dutch language) to the Dutch Parliament. She agreed that stricter EU legislation for innovative biotechnologies could lead to a competitive disadvantage for Dutch products and stated that the ECJ verdict makes it clear that the EU legislature should adjust the regulations for GE crops if it is deemed necessary or desirable. In the letter she further stated that the smallest possible legislative change to add new techniques to the existing exemptions is to list them in Annex IB of Directive 2001/18/EC, as earlier proposed by the Dutch Government on September 7, 2017.

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 FAS GAIN Report NL8052 - 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. Reportedly fourteen EU Member States supported to address the complications related to the current legal status of innovative biotechnologies. In the Council press release is was also stated that: "The 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".

In the Dutch Government Financial Budget for 2020 (in Dutch), published on September 17, 2019, the Dutch Cabinet stated that the Ministry of Infrastructure and Environment and the Ministry of Agriculture, Nature and Food Quality will inform the Dutch Parliament on how the Dutch Government will proceed on the issue of legislating innovative biotechnologies, in particular Crispr-Cas9.

f) Coexistence

In 2004, the Dutch agricultural sector and environmental NGOs agreed upon coexistence regulations which were accepted by the Dutch Ministry of Agriculture. The Product Board for Arable Crops was responsible for the implementation of the regulations. With the abolishment of this organization, the national coexistence regulation has been 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

or when GE crops are planted in the Netherlands. Despite the coexistence regulations, GE crops can be banned on a municipal and regional level. Currently, the Dutch city of Nijmegen and the Province of Friesland banned GE crops from being cultivated within their borders.

g) Labeling and Traceability

The Netherlands implemented EU legislation on labeling and traceability. Products containing 0.9 percent or more GE content, per ingredient, must be labeled as a product of biotechnology.

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.

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 can 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.

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 the Environment (MIE) 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 Genetically Modified Organisms Act.

m) International Treaties / Forums

The Netherlands is 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 OECD 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

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 plant breeding and propagation sector 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. The Dutch Farmers Organization (LTO) is pragmatic and in favor of innovative biotechnologies but is cautious due to the resistance of retailers and consumers, in particular consumers in key export markets such as Germany. 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 livestock sector benefits from the ready 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 FAS GAIN Report NL7021 - *The Netherlands Signs the European Soya Declaration*, dated July 24, 2017.

b) Market Acceptance / Studies

On June 13, 2019, the Dutch Rathenau Institute published the report "Genome editing in plants and crops'. The report presents options for legislating gene editing and proposes to modernize the current biotechnology policy focused on differences in risks of the techniques, while simultaneously taking account of ethical and societal factors.

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 upsetting nature's balance are often mentioned.

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 judged to be vague by the public. Most Dutch citizens support the use of modern biotechnology for the breeding of plants, but negatively view the application for the breeding of animals.

On October 10, 2017, the Dutch advisory body Commission Genetic Modification (COGEM) published the report: *Global Motivation or European Character? Four Scenarios for GMOs in European Agriculture*. The report offers a perspective on the consequences that the (lack of) cultivation and importation of "GMO"s (genetically modified organisms) can have on agriculture, science, business, and consumers in the Netherlands and Europe.

On March 23, 2017, the COGEM published the report: *The gentech debate, angles for a fruitful dialogue* (Dutch language). This lengthy report outlines the history of the debate about the use of biotechnology in the Netherlands.

On March 8, 2017, the COGEM published its advice: *CRISPR-Cas and targeted mutagenesis in plant breeding* (Dutch language). One of the conclusions is that the risks related to the use of targeted mutagenesis are lower than with the application of classical mutagenesis, and that the use of the technology cannot be detected in the end product. The COGEM advises to exempt targeted mutagenesis from EU biotech legislation.

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.

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. The export documentation does not declare the reproductive material is sourced 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 (LNV). The Animal Experiments Commission (DEC) assesses the incoming license requests for biomedical research experiments. The Dutch Committee on Animal Biotechnology (CBD) assesses the other incoming license requests. These 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 Genetically Modified Organisms.
In a letter (in Dutch) to the 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, the Dutch advisory body Commission on Genetic Modification (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 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.

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 FAS GAIN EU Biotechnology Annual.

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 FAS GAIN EU Biotechnology Annual.

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 FAS GAIN EU Biotechnology Annual.

e) Intellectual Property Rights

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 FAS GAIN EU Biotechnology Annual.

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.

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. So far, authorization of GE animals is limited to the use for medical research by universities and academic hospitals.

b) Market Acceptance / Studies

Generally, the public is not supportive of cloning or GE animals, and so the market reflects this position.

On May 9, 2019, the Netherlands Commission on Genetic Modification (COGEM) published the report: *Gene Drives: Experience with gene drive systems that may inform an environmental risk assessment*. The summary of the report states that "The results of field trials performed thus far demonstrated a varying degree of "success" of the gene drives. The drive-bearing organisms did not disperse beyond the target population. None of these trials revealed any negative impact on human health and environment."

On June 12, 2018, COGEM published the report: *CRISPR & Animals; Implications of Genome Editing for Policy and Society*. The report concludes that given the accelerating pace of technological change, the government and stakeholders should waste no time in adopting a position on the possible importation of genome-edited animals and products derived from them.

On December 12, 2017, COGEM published the report: *Event Report "Gene Edited Animals; Applications and Implications"*. On the October 19 and 20, 2017, COGEM organized the symposium "Gene edited animals; applications and implications" in Rotterdam, the Netherlands. During the meeting, international experts from Europe, China, North and South America, and Australia presented the latest developments in gene editing of animals.

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 judged as 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.

Attachments:

No Attachments