Required Report - public distribution

Date: 10/11/2016

GAIN Report Number: NL6034

Netherlands

Agricultural Biotechnology Annual

2016

Approved By:
Susan Phillips
Prepared By:
Bob Flach

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. An EU-wide overview is provided by the EU Consolidated Biotechnology Annual.

SECTION I: EXECUTIVE SUMMARY

The Dutch government and agricultural sector have a pragmatic approach towards the import of genetically engineered (GE) agricultural products. However, crop trials and commercial cultivation of biotech crops are effectively prevented by cumbersome regulations and by the threat of protests from environmental groups.

Innovative plant biotechnology (all new plant breeding techniques except genetic engineering) is a subject which has the strong attention of the Dutch Government based on its importance for the Dutch plant breeding sector, which ranks as the top exporter in the world. The current policy of Dutch government is that if products produced with the innovative biotechnologies are as safe as those produced with conventional breeding they must be exempt from labeling.

A concern of the government is that genetic engineering and patenting is creating a monopoly and a misbalance between breeder's rights and farmer's rights. As part of their Chair of the EU Council during the first half of 2016, the Dutch Government organized a symposium called "Finding the Balance." At this event, the European Commissioner for the internal market declared to provide specific interpretation of the current EU legislation, in particular related to the accessibility of genetic material.

The livestock sector does not include any GE animals nor do Dutch agricultural research institutes have them for research purposes. The Minister of Agriculture has stated that the Dutch Government does not oppose the European Commission (EC) proposal to ban food derived from cloned animals, but only if the regulation is practical and in line with international obligations.

Genetic Engineering (GE) = recombinant DNA technology = trans-genesis

Innovative plant biotechnology = new plant breeding technologies excluding GE products.

SECTION II: PLANT AND ANIMAL BIOTECHNOLOGY

TABLE OF CONTENTS

PART F: Marketing

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 in the next five years.

The database (in Dutch) of the National Institute for Public Health and the Environment (RIVM) reports that in 2016 ten licenses have been granted for research using GE techniques to develop medicines. Nine licenses were requested by hospitals and medical research institutes for research related to human health, and one license by a private company for the development of a veterinary drug.

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 assumption is based on limited producer interest, cumbersome regulations for approval and coexistence, 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 the 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 EU Biotechnology Report). Regarding this "opt-out" of cultivation option, the Dutch Government will determine per GE crop if they will allow cultivation. This judgment will be made by the Ministry of Economic Affairs on the basis of a scientific assessment framework and in consultation with a commission. Because the framework is not ready yet, the government implemented an opt-out for cultivation, or in other words a geographical restriction, for all pending approvals. The Dutch Rathenau Institute organized a stakeholder's dialogue about the set-up of the assessment framework. On June 30, 2016, the report of this event (not public) was presented to the Ministry of Economic Affairs.

c) Exports

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

d) Imports

The Netherlands imports large quantities of GE crops and derived products. Given the absence of cultivation, the Dutch do not import GE seed. Imports of GE processed consumer products are small as these products must be labeled. Imported GE crops and derived products are mainly soybeans 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 above 75 percent.

Imports of Soybeans and Meal, the Netherlands (1,000 MT)					
	2011	**2012**	**2013**	**2014**	**2015**
Soybeans					
-United States	589	810	1,066	1,124	1,717
-Brazil	1,047	1,034	1,271	1,420	794
Soybean meal					
-Brazil	3,122	3,288	3,437	2,720	2,329
-Argentina	2,097	1,426	1,209	1,383	935

Dutch position towards legislation for national "opt-out" of use:
The directive for opting out of cultivation was followed by an 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 by a letter (Dutch language) of their position. In the letter, the Cabinet strongly criticizes the proposal on two basic grounds. The main arguments are that the proposal is not science based and that the implementation will have negative effects on the economy. The Dutch Government made the distinction between opting out of cultivation and opting out of use based on the fact that growing crops is a local activity while use of inputs will have repercussions for trade which is in many cases an international activity.

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 NGOs.

f) Trade Barriers

The *slow approval process* of new GE events by the European Union has significantly affected U.S. exports to the Netherlands in particular corn, corn gluten feed (CGF) and Distillers' Dried Grains (DDG). Unpractical EU regulations for the allowed *Low Level Presence* (LLP) of GE materials in shipments have permanently affected the import of U.S. rice. *Mandatory labeling* of the presence of GE ingredients in food caused processors to avoid crops of which GE varieties are planted. This affected mainly the sourcing of vegetable oils, by which soybean oil was eliminated from the food ingredient list.

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 (I&E) - 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 Economic Affairs (EZ) - Responsible for GE legislation in the feed and seed area. Together with VWS, EZ plays an important role in the implementation of the EU Traceability and Labeling legislation. EZ 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 is also highly dependent on the 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 Dutch society's sentiments. Current national co-existence regulations practically ban the cultivation of GE events.

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. 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. 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. Both experiments are still taking place. The market introduction of the potato and apple variety is not expected within the next five years.

e) Innovative Biotechnologies

Dutch Position towards innovative biotechnologies:
The application of innovative biotechnologies is a dossier which has the keen attention and support of the Dutch Government. This support is based on the use of innovative biotechnologies as an important propagation tool for the Dutch plant breeding sector. 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. If so, they are exempt from the full requirements laid upon GE products in European Regulation EC/2001/18 (the regulation on cultivation), and can either be subject to the requirements of Annex IB of EC/2001/18 (considered a biotech product but safe) or left out totally (not considered a GE product). Techniques and methods of genetic modification used in plant production in Annex IB are not required to be labeled (mutagenesis and cell fusion).

In order to determine if the technology produced a safe food, the Dutch Government consults the studies of the European Food Safety Agency (EFSA) and the Institute of Food Safety of the Wageningen University (RIKILT) and National Institute for Public Health and the Environment (RIVM). The government has already decided that products produced through cis-genesis are as safe products as produced with conventional breeding, but there is no official position on whether this product should be considered a GE product yet.

In a letter (in Dutch) dated February 22, 2016, to the Dutch Parliament, the Dutch Minister of Agriculture, Martijn van Dam, stated that innovative biotechnologies can support Dutch policy objectives such as sustainability, food security and food safety. Examples provided in the letter are the development of a pest resistant rice and potato varieties. He further states that the Dutch Government is awaiting the judicial analysis of the European Commission (EC). Until the decision of the EC, the Dutch Government will judge innovative biotechnologies as equal to genetic engineering. The European Council has reportedly not yet taken a decision on the proposal.

f) Coexistence

In 2004, the Dutch agricultural sector and 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 being cultivated within their borders. With the adopted opt-out of cultivation, the

juridical status of the municipal and regional level bans is wavering.

g) Labeling

The Netherlands implements EU legislation that products that contain 0.9 percent or more GE content, per ingredient, must be labeled

h) Monitoring and Testing

The Netherlands Food and Consumer Product Safety Authority (NVWA) is actively testing feed and food imports on the presence of GE materials. The Dutch regulations for labeling, and sampling and testing are based on EU legislation (paragraph i on LLP).

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 genetically modified 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 legislation, and does not have their 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 to this concern has been that if needed, EU and international patent laws should be changed to assure biological material is freely available for the development of new varieties.

During the first half of 2016, the Netherlands chaired the EU Council. The misbalance between patent rights and farmers' rights was one of their priorities. The Dutch Government organized a symposium on May 18 and 19 called, "Finding the Balance", the European Commissioner for the internal market Elzbieta Bienkowska declared to provide specific interpretation of the current EU legislation, in particular related to the accessibility of genetic material.

l) Cartagena Protocol Ratification

In the Netherlands, the Ministry of Infrastructure and the Environment (I&E) 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 / Fora

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 has the opinion 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

On April 4, 2014, the Dutch Cabinet informed the Dutch Parliament of its position towards the application of biotechnology in plant and animal breeding (see GAIN Report NL4011 for more information). The Cabinet stated that the application of biotechnology in agriculture creates added value and can benefit to the global food security and sustainability of food production, but only if the risks are negligible.

PART C: MARKETING

a) Public / Private Opinions

Because GE crop plantings are absent and GE labeled food products are scarce, Dutch citizens as well as consumers are not conscious of the developments in agricultural biotechnology. If GE crops were planted and GE labeled food was on the market, NGOs would likely protest and instigate consumer unrest.

The Dutch Farmers Organization (LTO) is pragmatic and in favor of planting GE crops, but are cautious due to the resistance of retailers and consumers, in particular consumers in key export markets such as Germany.

The Dutch intensive livestock sector depends on feed imports from third countries, mainly soybean meal, which is mostly GE. There is no resistance by consumers as this meat produced with GE feed does not have to be labeled.

Plantum NL, the association for Dutch plant breeding and propagation sector has the opinion that the current EU legislation offers sufficient leeway to exempt innovative biotechnologies from the current EU restrictive legislation for GE crops. Plantum NL has further the position that biological material protected by patent rights should be freely available for the development of new varieties.

b) Market Acceptance / Studies

On June 14, 2016, the Dutch advisory body Commission Genetic Modification (COGEM) published the

report: Trendanalyse Biotechnologie 2016, Regelgeving Ontregeld (Trend Analysis Biotechnology 2016, Regulations Deregulate – in Dutch). The State Secretary of Health, Sharon Dijksma, presented the report to the Dutch Parliament. In a letter (in Dutch) to the Parliament she stated that the report concludes that biotech innovations are outpacing the regulatory process, and as a result the risk of the applications cannot be safeguarded. Dijksma concluded that the following policies must be future proof and must anticipate the fast pace of developments.

On November 4, 2015, the COGEM published the report: Opvattingen over genetische modificatie en genetisch gemodificeerde organismen (Opinions about genetic modification and genetic modified organisms – in Dutch). The report concluded that most citizens are not fundamentally against or pro GE technologies. The absence of direct and detectable advantages of GE technologies is the main reason for the lack of support by the Dutch citizens. Another important factor is the lack of trust of the citizens in the government and private sector compared to NGOs and universities.

On March 5, 2015, the COGEM published a report about the status of the biotechnology sector in the Netherlands: Economische analyse van de Nederlandse biotechnologiesector (Economic analysis of the Dutch biotechnology sector – in Dutch). One of the main conclusions of the report is that biotechnology is increasingly integrated in other sectors, but the economic activity of the agricultural biotech sector itself is stagnating. The report also stated that the difference between genetic engineering and other biotech practices is disappearing, which questions the practicality of the current legislation on GE crops.

CHAPTER II: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

a) Product Development

In the Netherlands, there are no genetically engineered (GE) animals under development that will be on the market in the coming five years. In the policy paper of April 4, 2014, the Dutch Cabinet stated that 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 the paper emphasized that animal welfare is an important consideration for the judgment.

b) Commercial Production

In the Netherlands, there are no GE or cloned animals used for commercial use. GE animals are authorized for use as laboratory animal for medical research at universities and academic hospitals. Annually, 15 to 20 licenses are granted. The largest group of GE animals is mice. The Dutch livestock sector does not keep GE animals nor do agricultural research institutes in the Netherlands keep them 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 import and further trade 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.

e) Trade Barriers

Currently there are no trade barriers related to animal biotechnology. Future legislation could, however, introduce barriers. Compulsory labeling of products derived from the offspring of clones will probably halt the import of these products. Labeling of clones or genetic material of clones will have less impact on sales as these labels are not seen by the end consumer.

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 Economic Affairs (EZ). 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 does not have any unacceptable consequences for the animal's health and welfare. Nor should there be any ethical objections against the proposed application. The rules for a biotechnology application request are laid down in the Animal Biotechnology Decree. The Netherlands Food and Consumer Product Safety Authority (NVWA) enforces these regulations.

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 Minister of Agriculture, Martijn van Dam, stated that the Dutch Government supports the temporary EU wide ban on cloning of farm animals. The Cabinet does not oppose the EC proposal to ban food from clones, but only if the regulation is practical and in line with international obligations. The Dutch Government has not made a decision about whether the prospective EU ban on the products from clones should also include products of the prodigy of clones. During the Dutch Presidency of the EU, the cloning of animals was not on the agenda.

On June 14, 2016, the COGEM published a report: Trendanalyse Biotechnologie 2016, Regelgeving

Ontregeld (Trend Analysis Biotechnology 2016, Regulations Deregulate – in Dutch). In a letter (in Dutch), State Secretary of Health, Sharon Dijksma presented the report to the Parliament and specifically referred to the risks of GE organisms with *gene drive*, as described in Science, Augustus 28 2015, Vol. 349, no. 6251, pp. 927-929. With *gene drive*, the GE organisms will solely produce GE offspring. The State Secretary concluded in the letter that the government will include the risks of *gene drive* in the assessment of the incoming license requests, and in addition will call for international measures.

b) Innovative Biotechnologies

The Netherlands has not yet decided to regulate innovative biotechnologies in animals. The Netherlands implements EU legislation.

c) 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.

d) Intellectual Property Rights

The Netherlands implements EU legislation, and does not have their own IPR laws that would protect patents on animal biotechnology.

e) International Treaties / Fora

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.

f) 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 of, but are not supportive of cloning and GE animals. Their policy is based on the public's aversion to the technique.

b) Market Acceptance / Studies

Dutch citizens and consumers do not support the use of cloning and/or genetic engineering technologies

by the animal agricultural sector. These practices are also not accepted by the majority of the Dutch livestock and dairy farmers, breeders or even the leading Dutch researchers.

In the Dutch society and government there is no consensus on what is ethically acceptable if such technologies are applied in the medical sector. This is why the Committee on Animal Biotechnology assesses all incoming license requests. Assessments are made on a case-by-case basis. These will eventually have to result in clear guidelines on what is or is not ethically acceptable in research involving cloning or genetic engineering of animals. So far, authorization of GE animals is limited to the use for medical research by universities and academic hospitals.

The COGEM investigated if the legislative framework and procedures in the Netherlands and Europe were equipped to deal with the market introduction of GE animals. In January 2012, a report was published: Genetically Modified Animals: A Wanted and Unwanted Reality.

In 2013, the Ministry of Economic Affairs held a public consultation on the use of cloning for agricultural practices. The study was conducted through online discussions between randomly selected citizens. The main conclusion of the consultation was that the public wants to be informed if the meat is produced from the progeny of clones. The study will be used as input for formulating the position of the Dutch Government. The final report of the study is not public.