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Report Highlights:

This report assesses the agricultural biotechnology sector in Sweden, and covers related production, trade and policies. It includes topics related to genetic engineering and innovative plant and animal biotechnologies. In this report the opinion of the Swedish government towards innovative biotechnologies for plant breeding is outlined and put in perspective with the opinions of the governments and advisory boards of Finland, Norway, Denmark and the Netherlands.

EXECUTIVE SUMMARY

As a member of the European Union (EU), Sweden fully applies EU regulations regarding approvals, traceability and labeling of genetically engineered (GE) products (known in the EU as genetically modified organisms or “GMOs”). Based on the specific climate conditions and strict domestic regulations for growing crops, the Swedish government supports the breeding of crops suitable for domestic production and acknowledges the importance of innovative plant biotechnology for achieving this. Since 2016, the Swedish government has argued to the European Commission (EC) and to the EU Court of Justice that the legal framework in the EU for GE products is not appropriate when applied to new plant breeding techniques. To put the opinion of the Swedish government in perspective, this report also lists the opinion of the government and advisory boards of Finland, Norway, Denmark and the Netherlands. While the Swedish farm sector is supportive of innovative plant biotechnology in plant breeding, they are excluding the use of GE crops and derived products in their supply chains.

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CHAPTER I: PLANT BIOTECHNOLOGY

PART A: PRODUCTION AND TRADE

a) Product Development

In the past, several seed companies in Sweden have developed their own genetically engineered (GE) varieties, including herbicide tolerant rapeseed, herbicide tolerant sugar beet, and starchy potato (Amflora). However, societal opposition and restrictive EU regulations have stopped commercialization. Currently, in Sweden, there are no GE crops under development that will be on the market within the next five years. The future market introduction of any gene edited crops, developed through innovative biotechnology, will be determined by future EU regulatory frameworks. At present, however, EU legislation is too restrictive to commercialize gene edited crops (see under PART B: POLICY, e) Innovative Biotechnologies).

Currently there are nine field experiments being conducted with GE and gene edited plants in Sweden (see under PART B: POLICY, d Field Testing). Unlike for instance Finland, a public-private organization

for plant breeding is absent in Sweden, which reportedly led to contraction of the domestic plant propagation sector over the past decade. However, the Swedish government has recently shown increased interest in the planting seed sector. After 2017, Sweden's [national food strategy](#) provides approximately SEK 40 million (approximately \$4.2 million) in annual support for plant breeding. The main reason for this increased interest and support is that Sweden has specific climate challenges in growing crops, with low temperatures and long days during the growing season, and generally stricter regulations for pesticide and fertilizer use compared to other EU Member States. The Swedish market is generally too small for global seed companies to develop specific crop varieties for these growing conditions. Another reason for increased interest in developing Sweden's plant seed sector is climate change -- the [Swedish farm sector](#) (in Swedish) is expecting changes in rain patterns and, potentially, increased pressure from pests.

b) Commercial Production

The only commercially cultivated biotech crop that has been planted in Sweden was the GE starchy potato, Amflora. Amflora was developed by BASF Plant Science and approved for cultivation in March 2010. It was grown in Sweden during the 2010/2011 season. Due to strong opposition to the use of genetic engineering for plant breeding in Europe, BASF decided to concentrate its future activities in markets outside of Europe. As a result, there has been no further cultivation of Amflora in Sweden.

In Sweden, there are also 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 the cumbersome EU regulations for approval, limited GE varieties available, and limited producer interest. The [only authorized crop for cultivation, MON810 Bt corn](#), is not suitable for cultivation in Northern Europe, and, accordingly, not of interest to Swedish farmers.

Swedish position towards legislation for national "opt-out" of cultivation:

Since 2015, it has been possible for an EU Member State to prohibit the cultivation of commercially approved GE plants in all or part of its territory through Directive EU/2015/412. Like other Nordic countries (with the exception of Denmark), Sweden has not implemented this directive because, as previously stated, there are no authorized GE crops for cultivation available which are suitable for cultivation in Northern Europe.

c) Exports

Sweden does not produce or export domestically produced GE crops or products.

d) Imports

Although [several GE soy varieties have received approval](#) to be imported into the EU (since 1998), shipments to Sweden have been very limited. This is because the Swedish meat and dairy industry voluntarily bans the use of GE feed. The livestock sector lifted its ban in 2006, but, under societal pressure, re-imposed the ban in 2011. There is no crushing of soybeans in Sweden. Most of the soy

which is used by the Swedish livestock and poultry sector is imported as soybean meal from a crusher in Norway (see Table 1). This crusher sources non-GM beans mainly from Brazil and Canada. Swedish imports of soybeans and derivatives from the United States and Argentina, if any, are incredibly limited (see Table 1). Like U.S. soybeans, U.S. feed corn has also been locked out of the market because of the industry's reluctance to use GE crops for feed. Currently, Sweden imports most of its feed corn from Russia and Poland.

The use of non-GE feed is creating a competitive disadvantage for Swedish livestock and dairy producers, as competitors are generally producing with the use of GE feed. These increased costs for Swedish farmers are already on top of higher costs associated with stricter national animal welfare standards. Despite the increase on cost, both the use of non-GE feed and Sweden's animal welfare conditions are used as marketing tools. The potentially negative media attention that could result from being the first to re-introduce GE feed is stopping all of Sweden's dairy and livestock producers from re-introducing GE feed into their supply chain.

Table 1. Imports of Soybeans, Meal and Oil, Sweden (1,000 mt)					
	2014	2015	2016	2017	2018
<i>Soybeans</i>	21,057	19,536	23,558	22,290	25,917
-Netherlands	300	276	1,178	4,068	9,984
-Denmark*	7,948	8,366	6,649	6,192	8,594
-Kazakhstan	5,639	2,677	6,478	2,640	3,839
-United States	20	0	54	154	0
<i>Soybean meal</i>	219,543	229,962	242,671	224,184	219,977
-Norway	115,389	133,921	141,767	140,345	136,132
-Russia	27,045	3,368	25,822	35,201	32,068
-Brazil	50,007	40,976	16,106	3,356	19,699
-Argentina	0	0	0	0	0
<i>Soybean oil</i>	29,983	29,927	34,392	35,454	25,740
-Norway	23,648	27,751	31,620	33,823	24,624

Source: Trade Data Monitor. *Note that imports from Denmark are re-exports.

Given the absence of cultivation, Sweden doesn't import GE seed. Moreover, imports of GE processed consumer products are small, as these products must be labeled as containing GE components.

e) Food Aid

Sweden is not a food aid recipient country, nor does it provide food aid. Instead, financial assistance is given by Sweden directly to recipients, through EU institutions, or through non-governmental organizations (NGOs).

f) Trade Barriers

Swedish imports from countries which grow predominantly GE soybean and corn varieties, mainly being the United States and Argentina, has always been limited. Mandatory labeling of the presence of GE ingredients in food caused processors to avoid products derived from GE crops, or avoiding imports from countries where GE crops are planted. The value of the opportunity lost in supplying ingredients and processed products to Sweden is impossible to quantify.

PART B: POLICY

a) Regulatory Framework

As an EU Member State, Sweden has implemented harmonized legislation regarding agricultural biotechnology.

- EU Directive 2001/18/EC is implemented mainly through the Swedish Environmental Code of 1998, as well as by Regulation 2002:1086 on the deliberate release of genetically modified organisms (GMOs) into the environment.
- The contained, not in the open field, use of GE microorganisms and GE plants is covered by Sweden Regulation 2000:271.
- EU Regulations, 1829/2003/EC, 1830/2003/EC and 1946/2003/EC, are directly applicable in all EU countries, including Sweden.

Responsibility for the monitoring and enforcement of laws and regulations on biotech in Sweden is mainly divided between the Ministry of Enterprise and Innovation, and the Ministry of the Environment.

- **The Ministry of Enterprise and Innovation** is responsible for matters relating to state-owned enterprises, private enterprises, rural and agricultural affairs, and regional growth. The Ministry has oversight over the use of biotechnology by the agricultural sector, related research, and field experiments. For additional information, see <https://www.government.se/government-of-sweden/ministry-of-enterprise-and-innovation/>.
- **The Ministry of the Environment** is responsible for the government's environmental and climate policy. The Ministry has oversight over the environmental aspects of the use of biotechnology. For additional information, see <https://www.government.se/government-of-sweden/ministry-of-the-environment/>.
- **The Ministry of Health and Social Affairs** is responsible for health-related issues, including medical biotechnology and food related issues. For additional information, see <https://www.government.se/government-of-sweden/ministry-of-health-and-social-affairs/>.

- **The Swedish Board of Agriculture** has oversight over activities with GE plants, animals, and feed. The activities include regulating the contained use, deliberate release, and introduction of GE feed and seed into the market. It is also responsible for the supervision of unintended involvement of GE material in non-GE plant varieties. For additional information, see <https://www.government.se/government-agencies/swedish-board-of-agriculture/>
- **The National Food Agency** is the competent authority for the control of foods containing, consisting of, or produced from GE organisms. Besides analyzing foodstuffs, the Agency is also responsible for control of labeling. For additional information, see <https://www.livsmedelsverket.se/en/>
- **The Swedish Gene Technology Advisory Board** monitors developments in the field of gene technology, including ethical considerations, and provides advice on its use to government, authorities and the public. Through its composition of politicians and researchers, the Board plays an important role as a bridge builder between the political sphere and the research community. For additional information, see <https://www.genteknik.se/> (in Swedish).
- **The Swedish Environmental Protection Agency** plays an advisory role, providing input to other authorities on issues (including deliberate release and market placement of “GMOs” and GE products). The regulatory authorities consult with the Swedish Environmental Protection Agency when they develop regulations and decisions concerning “GMOs.”
- **The Work Environment Authority** is responsible for the supervision of the contained use of GE microorganisms. The Authority has oversight over risks related to the environment and human health.

b) Approvals

The Government of Sweden is open minded but cautious towards the production and use of GE crops, feed and food. Within the EU, Sweden belongs to the “pragmatic” group of countries. In biotech policy discussions, Sweden normally tries to find solutions that are science-based as well as practical. Sweden has voted positively on almost all applications since the start of the approval process in 2004. Exceptions were the votes against the authorization of two GE maize events (Bt11 and 1507) on January 27, 2017, in the Regulatory Committee, and on March 27, 2017, in the Appeal Committee. The Swedish Ministry of Environment based their decision on the presence of insecticidal proteins in the GE maize varieties, which is in conflict with the policy of the Swedish Environmental Protection Agency to aim for a non-toxic environment ([Eriksson, 2017](#)).

c) Stacked or Pyramided Event Approvals

Sweden implements EU legislation.

d) Field Testing

Field experiments are regulated at the EU level by Directive 2001/18/EC, but decisions on permits are made at the national level. The directive has been implemented in Swedish legislation via the Environmental Code and Regulation (2002:1086) on the release of “GMOs” into the environment.

Sweden is the only country in the Nordic region where field trials are conducted with GE plants. Currently, there are nine field experiments being conducted with GE and gene edited plants in Sweden. The reason for the relatively large number of field tests is two-fold. First, the specific crop growing conditions, as stated under section a) Product Development, dictates the need for the breeding of suitable crops for domestic use. The second reason is that the decision-making process of the Swedish government for granting field experiment licenses is science-based and generally not politically influenced. Most of the field experiments, except for the experiments with potatoes, are for basic scientific purposes and not for applied science, with the goal to develop a specific commercial crop variety on the short term.

The Swedish Board of Agriculture makes a case-by-case assessment of field trial applications, and provides a [list of field trials](#) (in Swedish). Translated from the website, the list of current field trials in Sweden follows:

Crop	Change in Phenotype	Area (m²)	Permit Owner
Wheat	Increased oil content (T)	700	Swedish Agricultural University
Pear and apple	Improved rooting ability (T)	400	Swedish Agricultural University
Aspen	Increased biomass (T)	7,000	SweTree Technologies AB
Aspen	Study of gene expression (T)	10,000	Umeå University
Aspen	Change of wood structure (T)	12,000	Swedish Agricultural University
Aspen	Study of gene expression (T)	10,000	Umeå University
Camelina	Change of oil quality (T)	1,400	Swedish Agricultural University
Potato	Change of starch composition (C)	560	Swedish Agricultural University
Potato	Change of starch composition (C)	4,500	Lyckeby Starch AB

Field trials with wheat

The Swedish University of Agriculture is conducting GE wheat field trials during the period 2019-2023. In this wheat, the storage of energy has been redirected so that the seeds contain more oil and sugar and less starch. The gene used to modify the wheat has been isolated from oats. The wheat has also been modified with a gene that makes the plants tolerant to glufosinate (an herbicide).

Field trials with pear and apple rootstocks

The Swedish Agricultural University is also conducting GE pear and apple rootstock field trials from 2015-2019. The gene from *Agrobacterium rhizogenes* have been added to the root strains to evaluate the impact of gene transfer on growth characteristics (as well as to see the commercial potential).

Field trials with hybrid aspen

The Umeå University, the Swedish Agricultural University, and SweTree Technologies AB have received permission to conduct aspen field trials. The promoters were taken from cauliflower mosaic virus and eucalyptus to gain improved knowledge about growth, physiology, and wood properties. The future purpose is to produce trees with increased production of wood.

Field trials with *Camelina sativa*

The Swedish Agricultural University received permission to conduct field trials with GE *Camelina* during the years 2017 - 2021. The GE varieties have different oil compositions, and the purpose is to test the modifications under field conditions, such as cold tolerance, and to produce sufficient amounts of oil to allow for further experiments with the oil.

Field trials with potatoes

The Swedish Agricultural University is also conducting field trials with gene-edited potatoes during 2019 to 2023. The potato contains amylopectin starch which is naturally stable, making a chemical modification unnecessary, leading to a reduced use of chemicals in the starch industry.

Field trials with potatoes

Lyckeby Starch AB has applied for a permit for gene-edited potato field trials during the period 2019 to 2023. Genes were introduced using the gene editing technique CRISPR-Cas9, with as a result only amylopectin is produced.

For more information about the field experiments see <https://www.genteknik.se/yttranden/2019/> (in [Swedish](#))

e) Innovative Biotechnologies

As noted above, plant biotechnology, including innovative plant biotechnology, is conducted at many of the universities and research institutes in Sweden. Part of the development of the gene-editing tool, CRISPR-Cas9, was carried out at the Umeå University. In 2015, the Swedish Board of Agriculture issued an "[interpretation](#)" that CRISPR-Cas9-mutated plants which do not contain foreign DNA should be exempted from the EU "GMO" legislation.

On January 18, 2016, the interpretation was followed by a letter from the Swedish Ministry of Enterprise and Innovation to the EC Directorate General Health and Food Safety stating that the current technique-based legislation on "GMOs" is challenged by recent technical advances that have been realized. In the letter, the Ministry concluded that the EU legal framework for "GMOs" is not sufficient for handling some of the new genome-editing techniques. See attachment 1.

On January 27, 2017, the Swedish Ministry of Foreign Affairs (MFA) reinforced the position of the Ministry of Enterprise and Innovation, with a letter to the European Court of Justice (ECJ), regarding the French request to clarify the legal status of innovative plant biotechnologies. In the letter, the Swedish MFA stated that techniques resulting in targeted mutagenesis, including less than the

technical detection limit of 20 nucleotides, should not be legislated as “GMOs,” whereas techniques resulting in targeted insertion of more than 20 nucleotides should be legislated as “GMOs.” See attachment 2.

The [National Food Strategy for Sweden](#), ([full report 2016/17:104 in Swedish](#)), published in 2016, states that new technological methods and innovations should be used to safeguard access to local and regional varieties, and also to help maximize the use of production resources and ensure that agriculture adapts to a changing climate. The strategy further states (page 46) that when approving new varieties on the market, an assessment should be made based on the individual characteristics of each individual crop and its effect on human and animal health and the environment, regardless of which plant breeding technology was used.

On July 25, 2018, the European Court of Justice (ECJ) issued a 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 - EU Court Extends GMO Directive to New Plant Breeding Techniques](#), dated July 27, 2018.

On December 12, 2018, the Swedish Board of Agriculture published the document [“Consequences of the EC-ruling according to Swedish companies and research groups”](#). The analysis is based on interviews with the Swedish biotechnology and agricultural sector. The study concludes that the consequences of the ECJ judgement are that expensive authorization procedures will be enforced that will halt the development of improved crops and food products in the EU and redirect the development to countries outside the EU. In the same document, the National Food Agency states that next generation sequencing could be used to identify known genome edited crops. However, if information on the possible mutation is not available, the prospects for detecting are almost non-existent.

For more information see the Swedish policy position towards innovative biotechnology:

- <https://www.pgrip.org/wp-content/uploads/2018/11/Information-on-NBTs-in-Sweden.pdf>
- <https://onlinelibrary.wiley.com/doi/abs/10.1111/ppl.12661>
- <https://onlinelibrary.wiley.com/doi/full/10.1111/ppl.12740>

To help put the opinion of the Swedish government in perspective, below is a brief and non-exhaustive list of government opinions in the Nordics and The Netherlands.

Table 3. Government Opinions in the Nordics and The Netherlands

Date	Organization	Document	Position
February, 2014	Finnish Board for Gene Technology	Letter to EC	Plants developed with direct mutagenesis should fall outside the scope of the EU “GMO” legislation.
November 2015	Swedish Board of Agriculture	Interpretation	CRISPR-Cas9-mutated plants which do not contain any foreign DNA should be exempted from the EU “GMO” legislation.
January 2016	Swedish Ministry of Enterprise and Innovation	Letter to EC	Legal framework in the EU for “GMOs” is not appropriate for handling some of the new plant breeding techniques.
May, 2016	Finnish Board for Gene Technology	Interim Decision	CRISPR-modified progeny lines not containing foreign DNA should fall outside the scope of the EU “GMO” legislation.
January 2017	Swedish Ministry of Foreign Affairs	Written opinion referred to the Court of Justice of the European Union	GE plants resultant from targeted mutagenesis, containing less than the technical detection limit of 20 nucleotides, should not be considered a “GMO.”
September 2017	Dutch government	Proposal to the European Commission and EU Member States	Plants resulting from new breeding technologies, provided that they are at least equally safe as plants obtained by traditional breeding, should be considered GE crops, but should be exempted from the conditions laid out for GE plant varieties in Directive 2001/18/EC.
December 2018	Norwegian Biotechnology Advisory Board	Advice to the government	No obligation to notify changes that can arise naturally and can be achieved using conventional breeding methods.
June 2019	Danish Ethical Council	Statement	A change of the EU “GMO” approval procedure is necessary.

The position of the Finnish Board for Gene Technology

In 2014, the board sent a [letter](#) to the EC stating their opinion that plants developed with direct mutagenesis are outside the scope of the Finnish Gene Technology Act which implements the Directives 2001/18/EC and 2009/41/EC. In 2016, the board made the [interim decision \(in Swedish\)](#) that CRISPR-modified progeny lines not containing foreign DNA should fall outside the scope of EU the gene technology regulations.

The Dutch Proposal

The proposal recommends not listing all possible innovative plant breeding techniques on a case-by-case basis, as was done in the past, but rather to set forth criteria in Annex IB of 2001/18/EC 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](#).

The Norwegian Proposal

In December 2018, the Norwegian Biotechnology Advisory Board published its proposal: [A forward-looking regulatory framework for GMOs](#). The proposal has been developed in close dialogue with the public. It recommends basing the requirements for risk assessment and approval on a tiered system based on the genetic change(s) that have been made. From level 1 to 3 contribution to societal benefit, sustainability and ethics is required.

- Level 0: Temporary and non-heritable changes: Not covered by the Norwegian Gene Technology Act.
- Level 1: Changes that can arise naturally and can be achieved using conventional breeding methods: Obligation to notify.
- Level 2: Other species-specific genetic changes: Advanced assessment and approval needed.
- Level 3: Genetic changes that cross species barriers (transgenesis) or involve synthetic DNA sequences: Standard assessment and approval.

Danish Position on Gene-Editing

The Danish government has not yet taken a public position on the use and regulatory framework for innovative biotechnologies for plant breeding. However, the Ministry is concerned that public opinion from the Danish people towards gene-editing techniques remains negative. The Danish Ethical Council has recently published its opinion on gene-editing techniques which took a relatively positive position on the technology. The council recommends a change of the EU “GMO” approval procedure for GE plants with new traits. Its report (in English) titled: “GMO and ethics in a new era” is available online at: <http://www.etiskraad.dk/english/publications/gmo-and-ethics-in-a-new-era>.

The Dutch and Estonian Note to the Agricultural and Fisheries (AgriFish) Committee of the EU Council

On May 14, 2019, the Dutch Government, with support of the Estonian delegation, issued a [Note](#) with the subject “Follow up to the judgment of the Court of Justice in Case C-528/16” to the AgriFish

Committee of the EU Council. The Note stated 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 the request to address the complications related to the current legal status of innovative biotechnologies

The Finnish Proposal for a Study if the “GMO” Directive Fits for Purpose

On September 6, 2019, the Finnish Presidency submitted a Note to the Council of the European Union requesting the EC submit a study on the EU’s options for legislating new plant breeding techniques, taking into account Directive 2001/18/EC and the ECJ verdict. The proposed Council Decision states that since Directive 2001/18/EC has been adopted, new breeding techniques came available, which led to uncertainty whether these techniques fall under the scope of the Directive. Furthermore, it stated that the ECJ verdict raised questions for the national competent authorities on how to ensure compliance as products obtained by new mutagenesis methods cannot be distinguished from products resulting from natural mutation. Sweden reportedly wants costs estimates of implementing EU regulations included in the study. The Council established July 2021 as the deadline for the study. For more information see:

<https://data.consilium.europa.eu/doc/document/ST-11347-2019-REV-1/en/pdf> and the FAS [EU Biotechnology Annual](#) GAIN report drafted by FAS Paris.

f) Coexistence

In order to avoid the unintended presence of GE planting in conventional and organic products, the EC published guidelines on co-existence for different types of farming. EU Member States have, based on the EC guidelines, developed national strategies and best practices for co-existence. In May 2007, the Swedish government adopted its national framework for co-existence measures. In June 2008, the Swedish Board of Agriculture issued detailed regulations, including:

- Farmers who plan to cultivate GE crops must notify owners/users of neighboring land on November 1 the year before planting, at the latest.
- Farmers must notify authorities within two weeks after planting.
- The distance requirement for corn is 50 meters, for potato 3 meters. Shorter distances are allowed if agreed between the parties.

g) Labeling and Traceability

Sweden implements EU legislation which enforces the labeling of products containing 0.9 percent or more GE content, per ingredient. The Swedish government has not implemented GE-free labeling as it believes such labeling can be misleading, as most food products generally do not contain GE ingredients.

h) Monitoring and Testing

The Swedish Board of Agriculture and the National Food Agency are actively testing feed and food imports for the presence of GE materials. The Swedish regulations for labeling, sampling, and testing are based on EU legislation.

i) Low Level Presence (LLP) Policy

The Swedish 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 Swedish regulation establishes the methods of sampling and analysis of feed for the presence of GE product, which was authorized in a third country and the authorization procedure is pending in the EU for more than three months, and for GE products that were authorized in the EU but for which the authorization has expired.

j) Additional Regulatory Requirements

Sweden implements EU legislation.

k) Intellectual Property Rights (IPR)

Sweden implements EU legislation which protect patents on plant biotechnology.

l) Cartagena Protocol Ratification

In Sweden, the Ministry of Health and Social Affairs is responsible for the implementation of the Cartagena Protocol on Biosafety (CPB). Sweden has enforced the Protocol through the implementation of EU directives.

m) International Treaties / Forums

Sweden is member of the International Plant Protection Convention and the Codex Alimentarius.

n) Related Issues

No other related issues to report.

PART C: MARKETING

a) Public / Private Opinions

In a [press release \(in Swedish\)](#) of September 27, 2018, [the Federation of Swedish Farmers](#) (LRF) called for the breeding of new plant varieties to address climate change, and commented that new plant properties should be tested for health and environmental risks regardless of whether or not genetic

engineering has been used. LRF believes that the EU's current legislation on "GMOs" must be reviewed. Based on the concerns of Swedish farmers and consumers, LRF supports the labeling of food and feed containing GE ingredients.

The agricultural cooperative [Lantmännen](#), concurs with the statements of LRF. On its [website](#) it comments that genetic engineering in plant breeding can positively contribute towards a sustainable society. However, it also stated that it is aware that there are risks and that some consumers have concerns. It reaffirmed that its supply chain does not contain any materials from GE crops.

b) Market Acceptance / Studies

As mentioned under the section 1d) Imports, prior to 2006, Sweden did not import GE products or crops. During the 2006 – 2011, when the meat industry allowed GE feed, small quantities of GE soy products were imported. While demand for this product was limited, there was reportedly no negative reaction from the Swedish trade. The farmer, food processing, and retail sectors, however, remain concerned about the possibility of negative consumer reaction and anti-biotech demonstrations. These concerns were the reason for the meat industry to re-impose its ban in 2011.

CHAPTER II: ANIMAL BIOTECHNOLOGY

PART D: PRODUCTION AND TRADE

There are no genetically engineered (GE) animals for food production in Sweden. However, GE animals, mainly mice and banana flies, are used by universities and industry for biological, medical, and biomedical research.

a) Product Development

In Sweden there are no GE or cloned animals under development that will be on the market in the coming five years. For the application in agriculture, a clear position has not yet been taken, but animal welfare is an important consideration.

b) Commercial Production

In Sweden, there are no GE or cloned animals used for commercial use. GE animals are only authorized for use as laboratory animals for medical research at universities and academic hospitals. The largest group of GE animals are mice and banana flies. Neither the Swedish livestock sector nor Swedish agricultural research institutes keep GE animals for research purposes.

c) Exports

As domestic production of GE and cloned animals does not exist, Sweden does not export domestically produced GE or cloned animals or their reproductive materials.

d) Imports

There are no known imports of GE or cloned animals or their reproductive material.

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 could halt the import of these products. Labeling of clones or genetic material of clones will have less impact on sales as these labels will not be present on the end product and thus are not seen by the end consumer.

PART E: POLICY

a) Regulatory Framework

The Swedish Board of Agriculture is the competent authority for GE animals in Sweden. The Swedish Agency for Marine and Water Management is the authority responsible for the contained use, deliberate release, and market placement of GE aquatic organisms.

- The use of GE animals is regulated in the Board of Agriculture's Regulations on the Use of Genetically Modified Animals (SJVFS 1995:33) and the National Board of Fisheries Regulations on Genetically Modified Aquatic Organisms (FIFS 2004:2).
- The contained use of genetically modified animals is regulated via Regulation 2000:271.

Anyone using GE animals in contained conditions must apply for consent to use the premises, and then notify the Board of Agriculture of the intended (contained) use. Corresponding requirements apply to aquatic organisms which are the responsibility of the Swedish Agency for Marine and Water Management.

Industry and universities developing GE animals also need approval from the Swedish Work Environment Authority to ensure that the people handling animals in laboratories are not exposed to any risks. In addition, approval is needed from an animal ethic committee.

b) Approvals

Sweden implements EU legislation and does not have its own approval procedures for GE animals or cloning. For more information, see the FAS [EU Biotechnology Annual](#) GAIN report drafted by FAS Paris. The regulating framework for cloning or genetic engineering of animals has not recently been discussed by the Swedish government.

c) Innovative Biotechnologies

Sweden has not yet decided how to regulate innovative biotechnologies in animals. Sweden implements EU legislation. For more information see the FAS [EU Biotechnology Annual](#) GAIN report.

d) Labeling and Traceability

Sweden implements current EU legislation. As part of or in addition to EU legislation, the Swedish Government wants to implement a traceability scheme for reproductive material. For more information see the FAS [EU Biotechnology Annual](#) GAIN report.

e) Intellectual Property Rights (IPR)

Sweden implements EU legislation and does not have its own IPR laws that would protect patents on animal biotechnology. For more information see the FAS [EU Biotechnology Annual](#) GAIN report.

f) International Treaties / Forums

Sweden is a member of Codex Alimentarius (Codex), and the World Organization for Animal Health (OIE).

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 applying cloning or gene editing techniques in animal breeding. Their policy is based on the public's aversion to the use of genetic engineering of agricultural animals and would most likely not support the use of these techniques in Sweden. The use of animals for medical research aimed at finding cures for diseases is perceived to be more acceptable.

b) Market Acceptance / Studies

Generally, the public is not supportive of cloned or GE animals.

Attachments:

No Attachments.