Swedish perspectives on plant gene technologies

Policies and applications

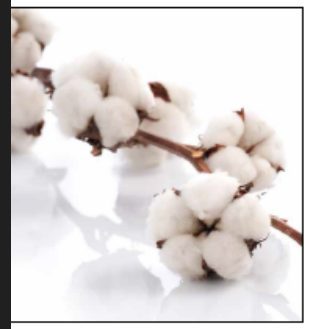
VKM-EFSA, 27 Oct 2017

Dennis Eriksson, PhD

Swedish University of Agricultural Sciences (SLU)

Jordbruks verket

Riskbedömning av genetiskt modifierade växter och växtprodukter



- I rapporten sammanfattas hur processen för hantering av ärenden om genetiskt modifierade organismer ser ut i Sverige och EU.
- Vi beskriver och ger exempel på hur vi bedömer risker med användning och odling.
- Jordbruksverket anser att den samlade riskbedömningen av genetiskt modifierade organismer som görs i EU är ändamålsenlig.

Rapport 2016:17

P7_TA(2014)0036

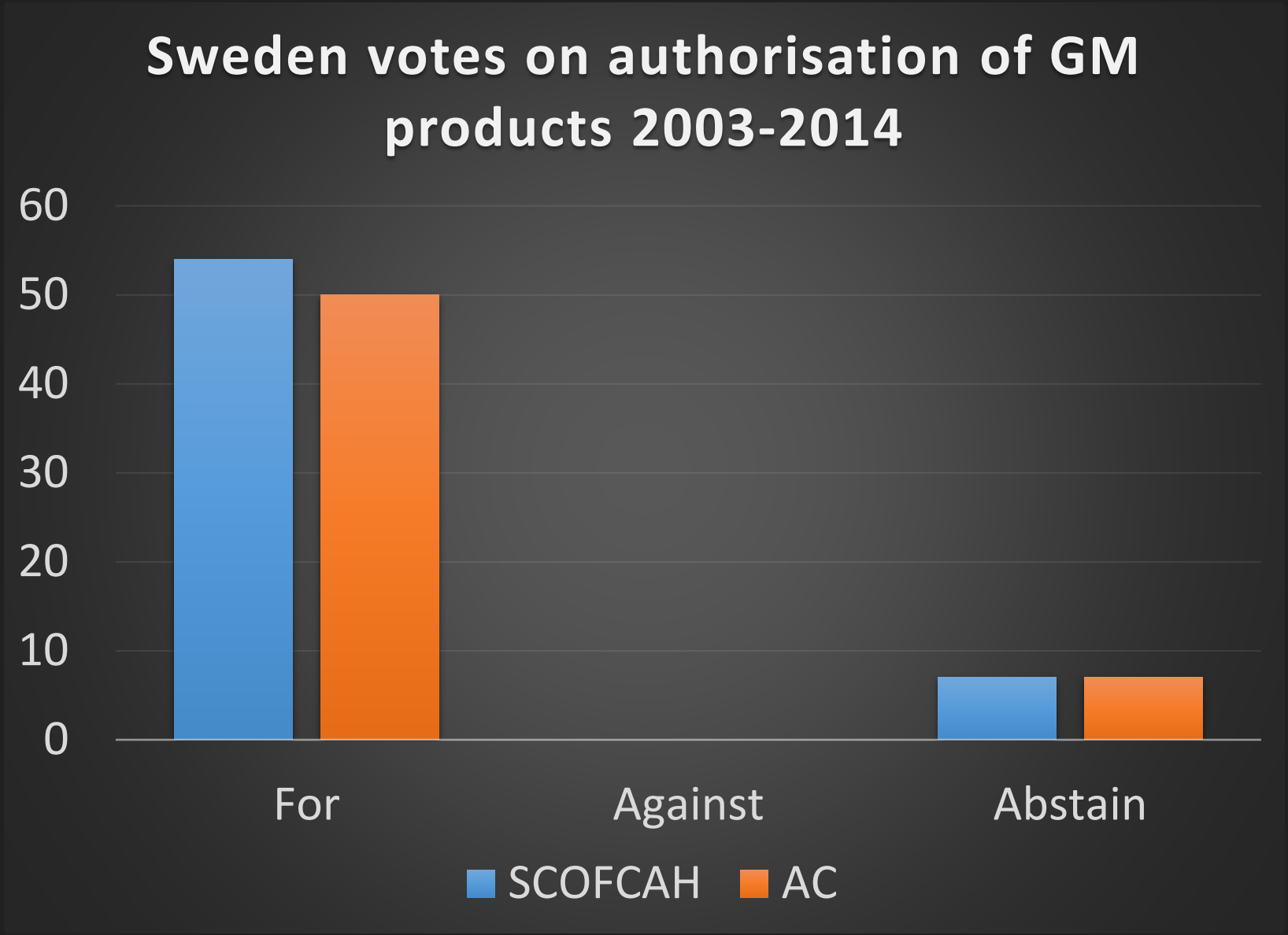
Placing on the market for cultivation of a genetically modified maize product

European Parliament resolution of 16 January 2014 on the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of the Council, of a maize product (Zea mays L., line 1507) genetically modified for resistance to certain lepidopteran pests (2013/2974(RSP))

The European Parliament,

– having regard to the proposal for a Council decision concerning the placing on the market for cultivation, in accordance with Directive 2001/18/EC of the European Parliament and of

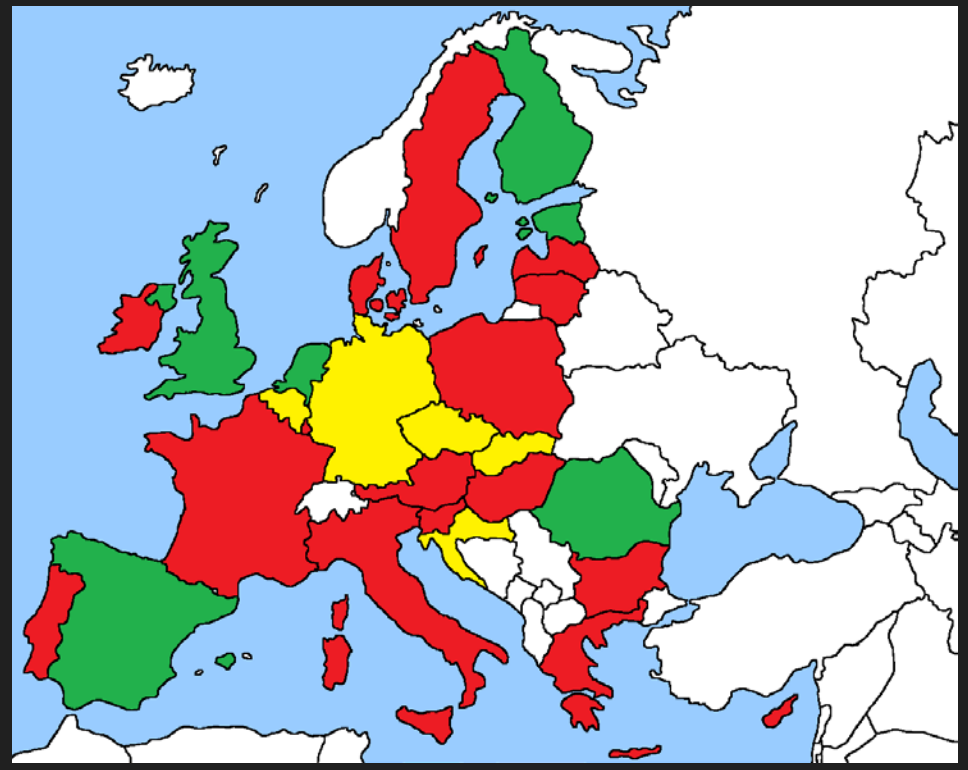
- The ERA should take into account the end use of the GM plant
- There can never be a 100% guarantee against long-term effects
- To not authorise products based on an idea of what consumers want is not proportionate



Reference:

Smart, R.D., Blum, M. & Wesseler, J. *GJAE* **64(4)**, 244-262 (2015).

Voting on HT/IR maize 27 March 2017



*“Sweden votes against the authorisation of cultivation of the genetically modified maize Bt11 with reference to the serious effects of **glufosinate-ammonium** on health and environment should the substance be released in to the environment.”*

“Glufosinate-ammonium is classified as a substance toxic for reproduction in category 1B which means that it does not fulfil the approval criteria for active substances according to the Regulation (EC) No 1107/2009.”

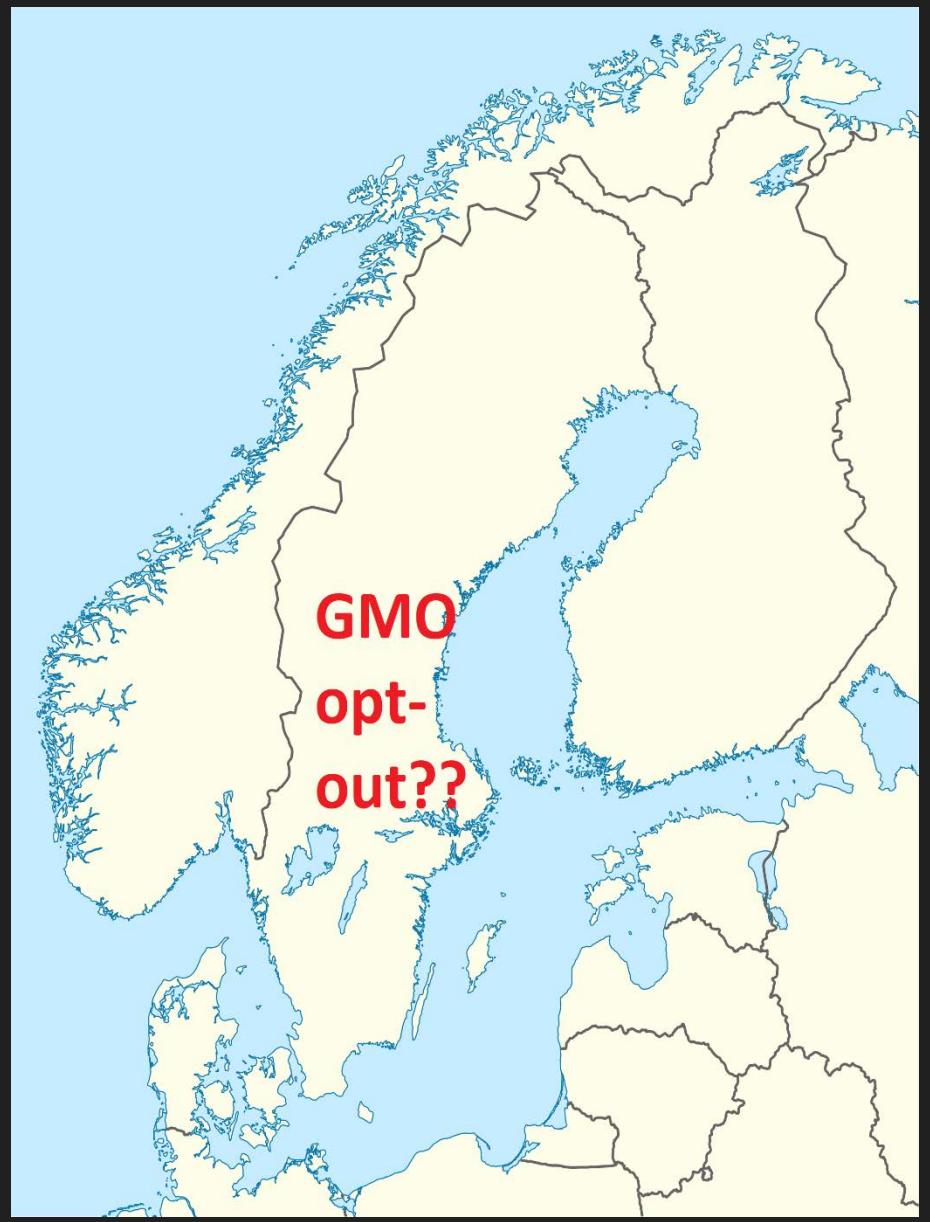
Möjlighet att begränsa eller förbjuda odling av genetiskt modifierade växter i Sverige

Slutbetänkande av Utredningen om begränsning av odling av genmodifierade växter

Stockholm 2016

STATENS OFFENTLIGA UTREDNINGAR

SOU 2016:22



(a) environmental policy objectives;

(b) town and country planning;

(c) land use;

(d) socioeconomic impacts;

(e) avoidance of GMO presence in other products without prejudice to Article 26a;

(f) agricultural policy objectives;

(g) public policy.

3 Oct 2016

France's Council of State today referred four questions on the legal status of mutagenesis techniques to the Court of Justice of the European Union (CJEU).

Article 3

Exemptions

1. This Directive shall not apply to organisms obtained through the techniques of genetic modification listed in Annex I B.

ANNEX I B

TECHNIQUES REFERRED TO IN ARTICLE 3

Techniques/methods of genetic modification yielding organisms to be excluded from the Directive, on the condition that they do not involve the use of recombinant nucleic acid molecules or genetically modified organisms other than those produced by one or more of the techniques/methods listed below are:

(1) mutagenesis,

(2) 'genetically modified organism (GMO)' means an organism, with the exception of human beings, in which the genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination;

(17) This Directive should not apply to organisms obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record.

Jordbruks verket

Swedish Board of Agriculture

Plant and Environment Department
Staffan Eklöf

INFORMATION

16-11-2015

CRISPR/Cas9 mutated Arabidopsis

This letter is to inform you that the Swedish Board of Agriculture (SBA) has made interpretations whether field trials with certain CRISPR/Cas9-mutated Arabidopsis have to be applied for as genetically modified organisms.

The SBA makes the interpretation that those plants in the description mutated by CRISPR / Cas9 and which do not contain any foreign DNA are exempted from the GM legislation.

CRISPR / Cas9 can be used in many different ways. We have made an assessment only of the specific plants described. The assessment does not necessarily apply to other plants developed with CRISPR / Cas9.

We have informed the universities that SBA´s interpretation may be subject to change if there will be a common interpretation of the definitions and exemptions at the EU level. We have also urged for caution during cultivation, as the plant's legal status might change rapidly.

Background

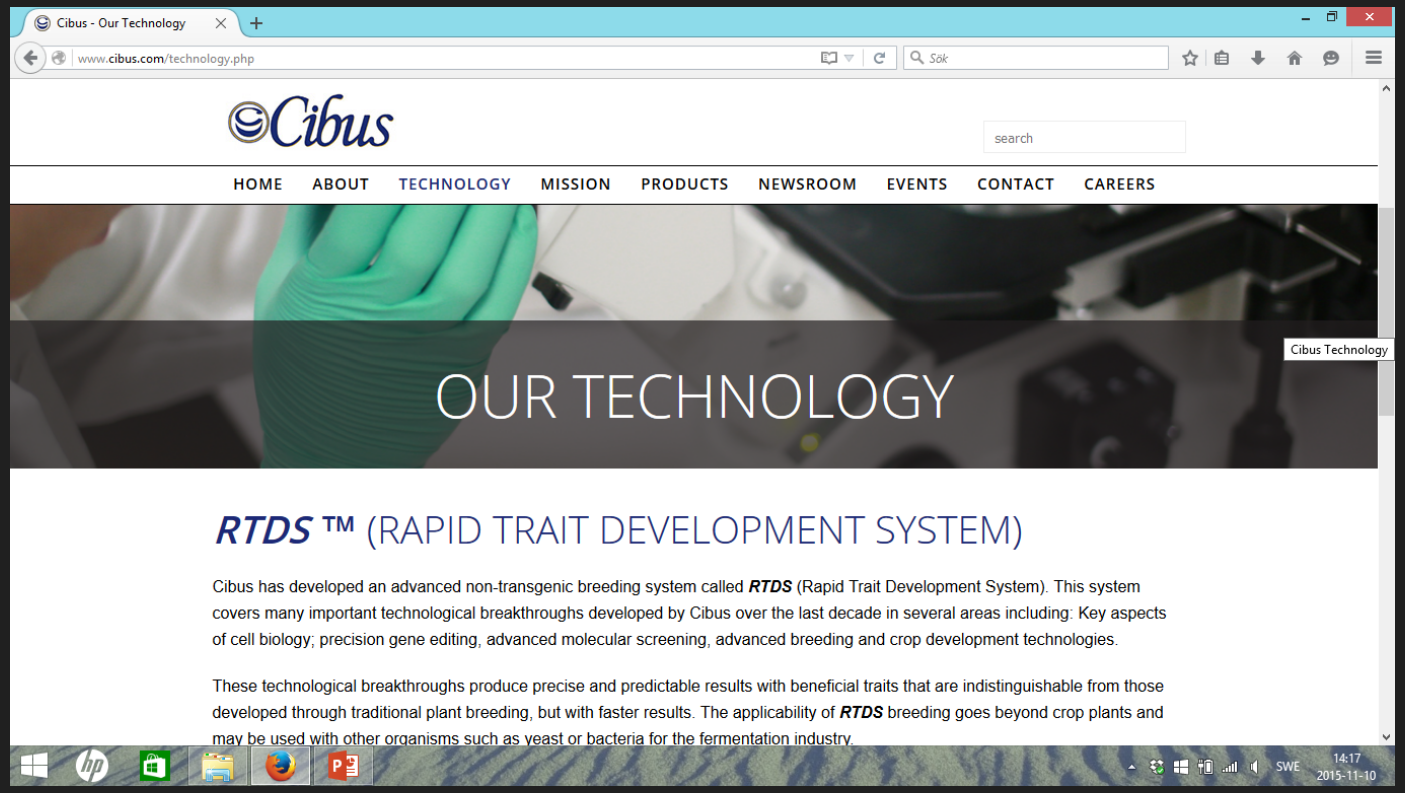
The SBA has received questions from two separate universities if they have to apply for field release in accordance with the GM legislation for thale cress modified with the CRISPR/Cas9 technique.

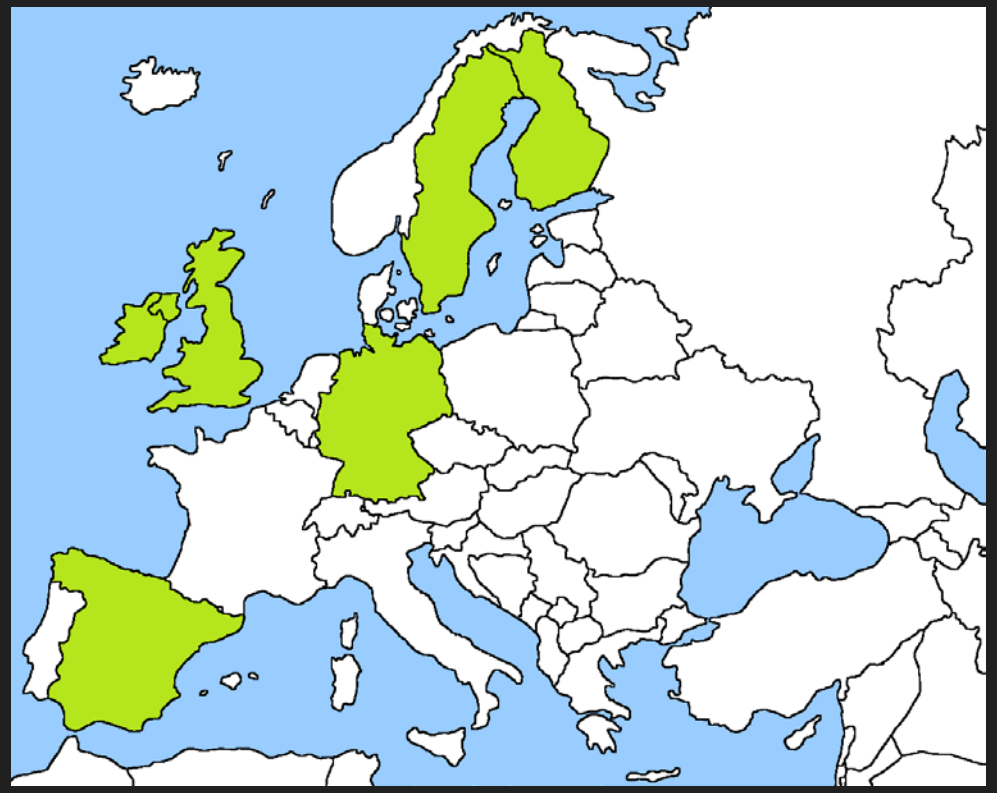
The plants are described to be transformed with Agrobacterium with a T-DNA encoding nuclease Cas9 and a sequence encoding a (single guide) sgRNA. This CRISPR / Cas9 system causes a site-specific double-strand break in the plant's DNA, which is repaired by the cell's own building blocks. During this repair certain mutations can occur. A template oligonucleotide, or a so-called gene targeting (GT) cassette in the T-DNA for mutation will not be used. Therefore, modification results in a double-strand break in the plant DNA with the re-ligation of chromosomal ends using the cell's own system without a foreign DNA sequence incorporated. The target sequence in the plant's DNA can only be mutated using the cell's own repair system, via so-called non-homologous end-joining. One or a few bases may be lost or added. In some of the plants they are to use two double-strand breaks, which leads to that the intervening DNA sequence is lost.

There are two types of plants. Plants in which mutations as described above have been made and the T-DNA is removed by crossing and plants with the same mutation but carrying T-DNA. Either as a result of where the plants' properties have been restored by transformation using Agrobacterium, so-called

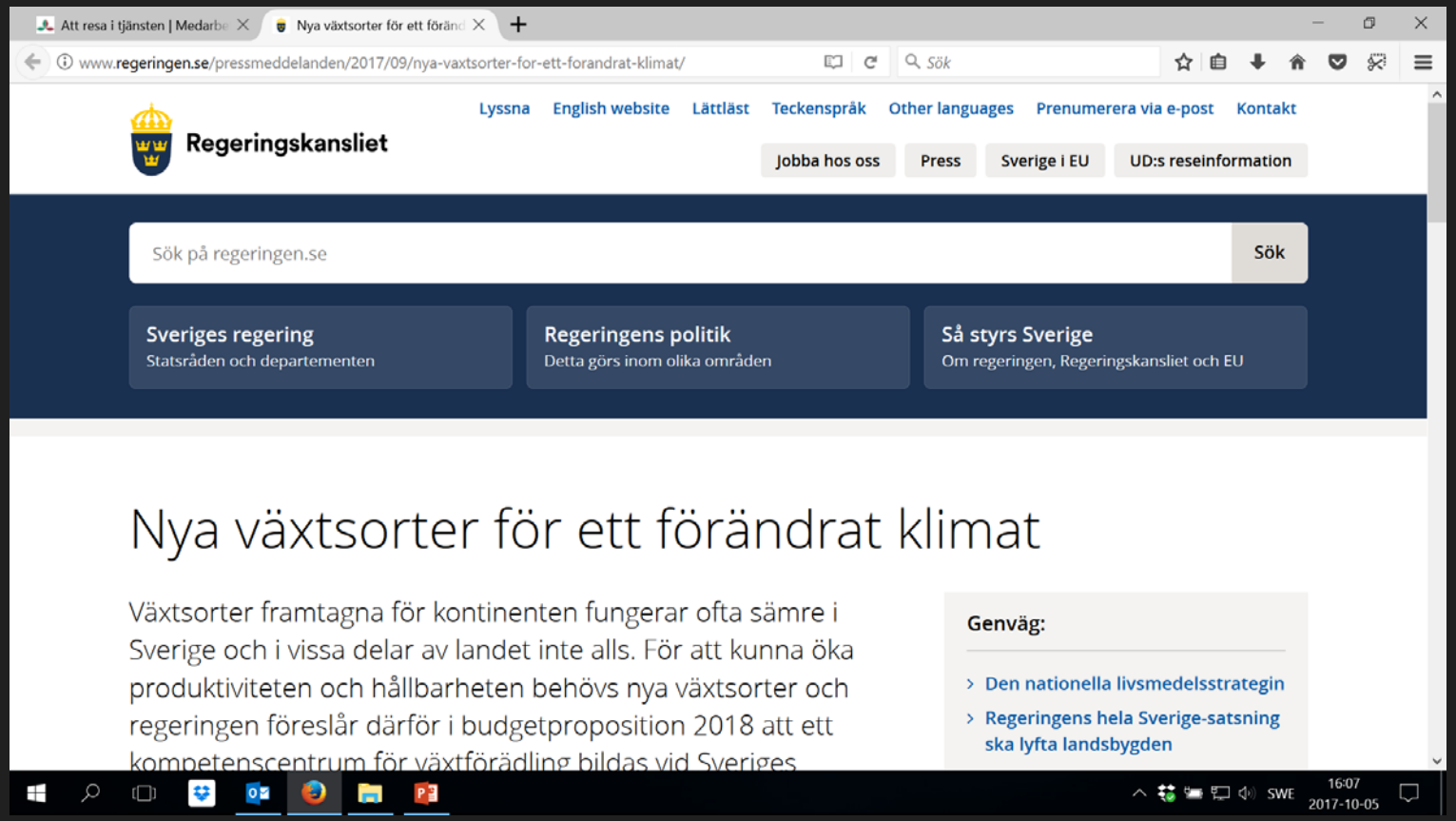
Swedish Govt to DG SANTE 18.01.2016:

*”In general, the legal system should be **proportionate to possible risks of the products**, handled on a case-by-case basis and not hinder innovation or place excessive financial burden on small or medium sized enterprises”*





Herbicide-tolerant rapeseed developed by ODM



Recent Swedish Government investment in plant breeding

Regeringens proposition
2016/17:104

En livsmedelsstrategi för Sverige – fler jobb och hållbar tillväxt i hela landet

Prop.
2016/17:104

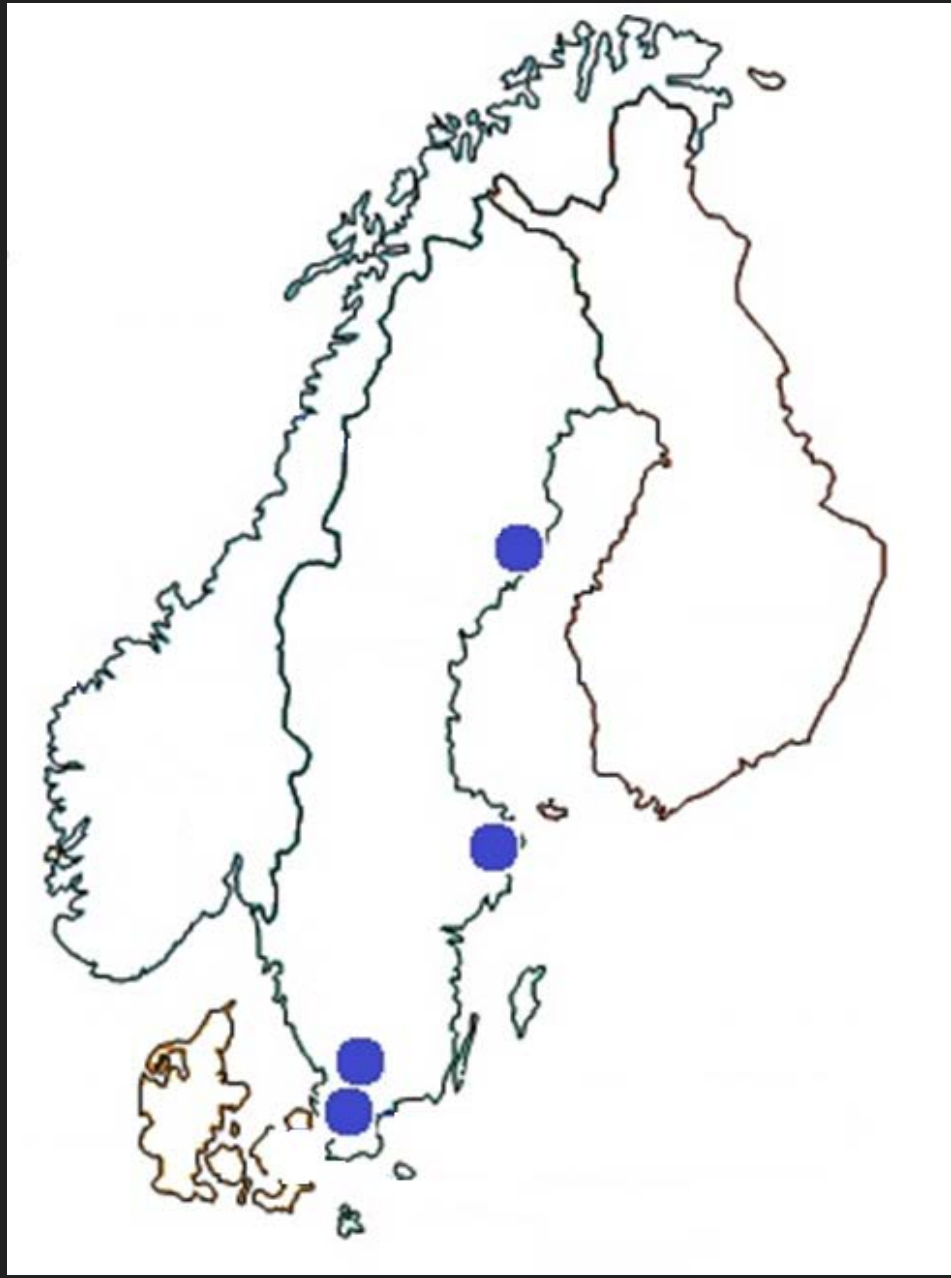
Regeringen överlämnar denna proposition till riksdagen.

Stockholm den 26 januari 2017

”For the approval of a novel event, an assessment should be carried out based on the impact of the crop´s traits on human health and the environment, ***regardless of which breeding technique has been used****”*

N.B. This is NOT an official translation of the original document, nor has the translation been approved by the Swedish Government

SLU



Umeå Plant Science Centre
a centre of Excellence

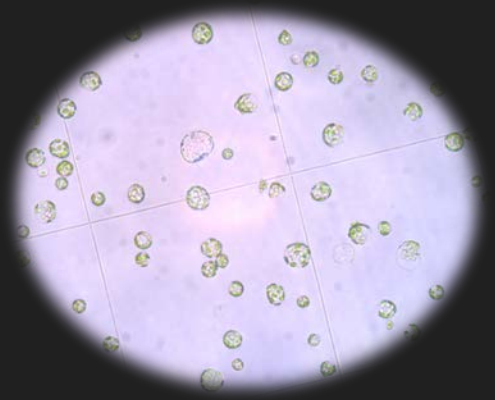
LINNEAN CENTRE
for Plant Biology in Uppsala

PLANTLINK

ScanOats

Precision breeding of oilseed rape, *Lepidium campestre* and potato

- Using CRISPR/Cas technique to produce mutation lines through protoplast approach
- Target traits: disease resistance, seed yield, herbicide resistance and oil qualities, starch quality



Project supported by Mistra Biotech and FORMAS in collaboration with Lantmännen

Source: Li-Hua Zhu, SLU, Alnarp

“The political fight for the next ten years will be linking science to policy”

EU Commissioner Carlos Moedas

Acknowledgments

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