BIOTECH LOBBY'S PUSH FOR NEW GMOS TO ESCAPE REGULATION

'New Breeding Techniques' the next step in corporate control over our food?

The biotech industry is staging an audacious bid to have a whole new generation of genetic engineering techniques excluded from European regulations. The pending decision of the European Commission on the regulation of these so-called 'new GMOs' represents a climax point in the ongoing below-the-radar attack by industry on GM laws.

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Written by
Nina Holland

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Editor
Ann Doherty

Design and layout
Ana Luísa Lages

Corporate Europe Observatory

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1. Introduction

The EU's GM regulations have long been a thorn in the biotech industry's side. For their lobbyists, the Commission decision presents a unique opportunity to twist the interpretation of these rules – including the very definition of a GMO – so as to exclude the new genetic engineering techniques from their scope. This goes alongside ongoing industry attacks on the application of the precautionary principle – the basis of EU GM regulations – to novel food production techniques.

New genetic engineering techniques, which have emerged since Europe's GMO law was introduced in 2001, are currently being applied by developers to food crops, trees, farm animals and insects. If the industry lobby campaign is successful, new GM organisms and foods – produced by techniques including oligonucleotide-directed mutagenesis (ODM), agroinfiltration and zinc finger nuclease technology (ZFN) - could enter the environment and the food chain untested, untraceable and unlabeled. Dozens of patents have already been filed in this field by the big agrochemical corporations like Bayer, BASF, Dow Agrosciences and Monsanto.

Due to widespread consumer rejection of GMOs, invisibility is vital for the commercial success of any new genetically engineered product in Europe. Their unregulated mass release could however have far-reaching consequences for the environment, food safety and consumer choice. Therefore, calls from farmers and environmental groups to regulate the new GM are increasing. The techniques in question each bring their own set of risks and uncertainties. Technical reports and legal analyses by government bodies and NGOs have concluded that GM 2.0 should not escape the EU GM regulations.[1] Whilst some risks are similar to those associated with GM 1.0, there are also serious additional concerns.[2]

To further its cause, industry has set up a dedicated, EU-level lobbying vehicle – the New Breeding Techniques Platform – with the mission of having as many of the new GM t echniques as possible excluded from EU GM regulations. This platform is run by Schuttelaar & Partners, a Dutch lobby and PR firm with a shady reputation for pro-GM lobbying. At the same time, individual companies have been pressing various European governments to clarify the legal status of the new genetic engineering techniques, while announcing plans to field trial them in those countries. Furthermore, certain governments have been actively advocating the deregulation of new GM techniques at the EU level.

The ongoing negotiations around the Transatlantic Trade and Investment Partnership (TTIP) are an additional source of political pressure on European decision makers. In this context, industry lobby groups have presented the regulation of new GM techniques as a trade concern to both US and EU officials,[3] claiming that the innovative nature and competitiveness of the European plant breeding (read: biotech) sector is at stake.

After contemplating this question for eight years, the Commission finally plans to publish a draft decision in February 2016. This briefing, based on documents released by the European Commission following freedom of information requests, illuminates the efforts made over the past three years by the industry lobby to have the new GM techniques deregulated. In addition, a first case study highlights the Dutch lobby campaign for the deregulation of cisgenesis, and a second one looks at Canadian company Cibus's push for the deregulation of its ODM oilseed rape.

2. A Lengthy Process

The European Commission turned its attention to the new GM techniques eight years ago, setting up a 'New Techniques Working Group' (NTWG) in October 2007 to assess whether the GM techniques listed above give rise to products falling within the scope of the GMO legislation. However, its final report showed that the working group was divided on the regulatory status of some of the techniques, therefore leaving the Commission with no clear plan of action.[4]

What are the new GM techniques?

The list of new GM techniques currently being considered by the Commission includes Oligonucleotide-Directed Mutagenesis (ODM); Zinc Finger Nuclease technology (ZFN) comprising ZFN-1, ZFN-2 and ZFN-3; Cisgenesis and Intragenesis; Grafting; Agroinfiltration; RNA-dependent DNA methylation (RdDM); and Reverse Breeding.[5] Most of these techniques are also called 'gene editing editing' techniques: instead of introducing genetic traits from another organism the genome can be directly 'rewritten' in the cells.[6]

Indeed, companies appear to be deliberately investing in techniques designed to circumvent the EU's GMO regulations. As an expert for the US Consumer Union has noted, "All these new technologies are ways to weasel around a very narrow definition of transgenic. I would consider that misleading to the public."[7] An industry lobby document sent to EU decision makers in 2013 could not be clearer about the industry's motivation to develop new GM techniques: they were developed "as a response to the de facto moratorium on GMOs that currently exists in Europe."[8] These investments, and the many related patent applications, now demand a financial return.

In parallel to the analysis carried out by this Working Group, the Commission requested opinions from the European Food Safety Agency (EFSA) about the risks posed by cisgenesis, intragenesis and Zinc Finger Nuclease 3, and whether existing risk assessment methods were adequate for evaluating them.[9] [10]

In 2012, the Commission reported that it was working with member states to find the best way forward in clarifying the regulatory status of the new techniques.[12] In a presentation to the European Seed Association, the Commission claimed to be looking not only at the legal aspects, but also at "safety considerations, the approach in third countries, the chances and risks involved, and the view of European plant breeders".[13]

Just months later, at a meeting with the industry-led NBT Platform, the Commission had changed course. It was later clarified that due to "the absence of consensus amongst the main political EU actors, reflecting the public hostility to GMOs", the Commission had opted for a legal guidance document interpreting Directive 2001/18, rather than for new legislation. This means that the European Parliament plays no formal role, and that member states are expected to follow the Commission's recommendations. In the case of disagreement, the European Court of Justice has the final say.[14]

The Commission has time and time again postponed the deadline for delivering the legal guidance document. In response to the many queries from industry and member states on its progress, the standard response has been that assessing the new techniques in the light of Directive 2001/18 "... is complex and requires a thorough technical and legal analysis".[15]

As the Commission indicated, the member states were divided. Certain EU governments, including the UK, the Netherlands and Germany, pressured the Commission to deregulate one or more of the techniques. The Netherlands for instance has invested considerable public research funding in promoting the cisgenic GMOs developed by Wageningen University, and the Commission has been pressured by Dutch Ministries, the Permanent Representation in Brussels, the national parliament, and Dutch MEPs. (See case study *Of apples and potatoes: the Dutch lobby for the deregulation of cisgenesis*, case study 1).

EFSA opinions on three techniques

With respect to cisgenesis and intragenesis, EFSA concluded that while intragenic plants would generate similar risks to transgenic ones, cisgenic plants could be compared to conventionally bred plants. However, the agency clarified that "all of these breeding methods can produce variable frequencies and severities of unintended effects. The frequency of unintended changes may differ between breeding techniques and their occurrence cannot be predicted and needs to be assessed case by case."[11] Furthermore, EFSA opined that ZFN-3 requires in principle the same risk assessment that is currently applied to GMOs, but that on a case-by-case basis "lesser amounts of data may be needed" for plants developed using this technique.

Not surprisingly, corporations have been itching to get started on field trials of the new GM crops. Between 2012 and 2014, BASF[16] and the Canadian company Cibus (among others) approached several member states, including the UK, Sweden and Finland, to ascertain the regulatory status of one of the techniques – Oligonucleotide-Directed Mutagenesis (ODM) – and to obtain clearance to field trial ODM herbicide-tolerant oilseed rape without having to undergo the regulatory risk assessment required of GMOs. (See case study *'Canadian company railroads EU decision making on new GM'*, case study 2).

This resulted in the Finnish government complaining to the Commission about the lack of clarity of direction on ODM, leaving the national competent authorities "in a legally challenging position" since they were obliged to respond to the companies.[17] Helsinki gave the Commission an April 2014 deadline to respond, but again the Commission told them to be patient.[18]

3. 'New Breeding Techniques Platform': corporations unite to deregulate GMOs

The trail of Freedom of Information requests over the past three years to the European Commission illuminates industry's efforts to have new genetic engineering techniques escape regulation. These efforts are coordinated by the New Breeding Techniques (NBT) Platform, whose objective is to have "all NBTs – or as many techniques as possible – exempt from GM legislation".[19] The Brussels office of Dutch lobby and public relations firm Schuttelaar & Partners (their motto: "science-based consultancy with sense") was hired to chair the NBT Platform and coordinate its lobby activities.

This was perhaps not a surprising choice, as company materials show that Schuttelaar & Partners' recent clientèle includes various biotech industry actors whose interests are served by the NBT Platform (for example Syngenta, Bayer CropScience, Dow AgroSciences, biotech lobby association EuropaBio and Inova Fruit). Also, the firm has not shunned highly damaging industry campaigns in the past: its first triumph was tricking decision makers into allowing Monsanto's herbicide-tolerant soy to flood the European market (See Box *'Schuttelaar & Partners: no novice to below-theradar lobby campaigns for biotech clients'*).

Any self-respecting PR firm designing a lobbying campaign will start off by rebranding its client's product and developing a new lexicon to pitch it to decision makers.

The NBT Platform, with its very name, has rebranded the new GM techniques as 'new breeding techniques' to make them sound different from 'genetic engineering'. Not without success: the European Commission and other regulatory bodies have fully adopted this term in their communication on the topic. Angelika Hilbeck, senior researcher at the Swiss Federal Institute of Technology, says: "'New breeding techniques' is a misleading term, precisely because the users of these techniques aim to avoid any breeding. They simply allow the maintenance of a successful market variety, and the improvement of an agronomic problem that primarily arises from monoculture production methods

Schuttelaar & Partners: no novice to below-theradar lobby campaigns for biotech clients

In 1995, the firm was hired by Monsanto to secure a smooth introduction for the first imports of a GM crop – Monsanto's herbicide-tolerant Roundup Ready soy – to Europe.[20] Schuttelaar & Partners was set up by Marcel Schuttelaar, a former campaigner for Friends of the Earth Netherlands. Familiar with Monsanto's adversaries as an insider and an outsider, he was the ideal man for the job. The strategy chosen was to 'let sleeping dogs lie': carefully injecting tranquillising messages into the right ears in order to avoid a sudden outcry from media and consumer organisations. The lobby firm – not hindered by a lack of evidence - stressed the 'benefits' of Roundup Ready soy, such as reduced pesticide use (a claim that has proven to be untrue).

By subtly expanding the European market, Schuttelaar & Partners helped pave the way for the further expansion of GM soy monocultures in South America. Ironically, 15 years later, the firm was hired by and participated in the Round Table on Responsible Soy (RTRS), which includes Monsanto in its membership.[21] The RTRS is a voluntary labelling scheme that certifies GM Roundup Ready soy as 'responsible', although its empty criteria do nothing to protect local communities or reduce deforestation and pesticide use.[22]

that promote disease and the prevalence of pests. The products will be sold under the same familiar names, except they are now patented and – if industry gets its way - not labelled as GM. The techniques are non-innovative, and just like GM 1.0, are primarily a business model."

Other labels in the new lexicon, such as 'gene editing' or 'genome editing', are used to emphasise surgical precision and to suggest absolute technological control of the genetic engineering process. However, as Hilbeck points out, precision in changing an organism's genetic makeup is not equivalent to safety if you do not fully understand what you are changing and the knockon impacts. "It's like changing letters in words and words in text in a language one does not understand. That can be done with precision and control, yet with complete oblivion to the meaning", she says.

Another key ingredient is to develop a narrative that tells how indispensable the product will be for the greater good – even if you can't come up with anything new. (See box *'New GM, same old pitch?'*).

Schuttelaar & Partners describes the work of the NBT Platform as providing decision makers with

New GM, same old pitch?

So why do we need a new generation of GM? The NBT Platform and other deregulation advocates echoe the arguments in favour of introducing GM crops 20 years ago in their pitch for the new GM techniques.[23] [24] [25] [26] They invariably cite some of the key challenges faced by society today, notably "rapid world population growth, climate change, and increasing scarcity of resources such as soil and water".[27] New GM techniques, it is said, will come to the rescue by massively improving the precision and speed of the plant breeding process. Important objectives allegedly include pest resistance and drought tolerance. Yet the very first new GM crop in the pipeline, developed by the Canadian company Cibus, is another herbicide-tolerant oilseed rape. Herbicide-tolerant GM crops have waged social and environmental havoc in the countries where they are mass produced.[28] Many GM 2.0 patent applications are related to traits such as herbicide-tolerance, insecticide production and changed oil composition - the same as GM 1.0.[29] Furthermore, the claims about the benefits of GM 1.0 have been refuted time and again.[30]

"independent science-based information" on the techniques, and generating awareness about "their widespread benefits" for the European economy.[31] [32] But the NBT Platform is far from independent, with the private sector making up the bulk of its membership and providing most of the funding. The membership fee structure, as provided on the Platform's website, lists annual subscription fees of €7,000 for Small and Medium-sized Enterprises (SMEs), €22,500 for large companies, and €2,500 for scientific institutions.[33]

However, none of this is evident from the EU Transparency Register entries of the NBT Platform and Schuttelaar & Partners. In fact, the entries of both parties exemplify the often meaningless, incomplete and incorrect information provided by corporations and lobby firms to this register. In this case, the NBT Platform's first listing in the Transparency Register is from April 2015, at least three years after its foundation. The connection to Schuttelaar & Partners is not mentioned, and neither the Platform members nor the funding sources are disclosed.[34] (Also see box *'Transparency register generates confusing and incorrect data on NBT Platform'*).

There is more information available on the NBT Platform's own website, but this was only launched in July 2015. The site lists the following members: Syngenta, KeyGene, Inova Fruit, SESVanderHave, Rijk Zwaan, Meiogenix, SweTree Technologies, Semillas Fitó, Enza Zaden, Rothamsted Research, VIB (Flemish Biotechnology Institute), Fondazione Edmund Mach and the John Innes Centre.[36] Commission documents however indicate that Dow Agrosciences and Bayer CropScience's vegetable seed business Nunhems were also at some point members of the Platform and, in any case, attended NBT meetings.[37] [38]

The NBT Platform does not let an opportunity pass to stress the interests of SMEs and research institutes in its lobby to get new GM deregulated. However, taking the EU definition of a SME as a company with fewer than 250 employees, only three Platform members qualify: KeyGene, Meiogenix and SweTree Technologies.[39] Furthermore, some of the 'public' research institutes that the NBT Platform represents have strong financial ties with industry. For instance, Rothamsted Research (UK) has many joint projects with agribusiness corporations.[40] And no less than one third of the general council membership of the Flemish Biotechnology Institute (VIB) is made up of industry representatives, including Syngenta and Bayer.[41]

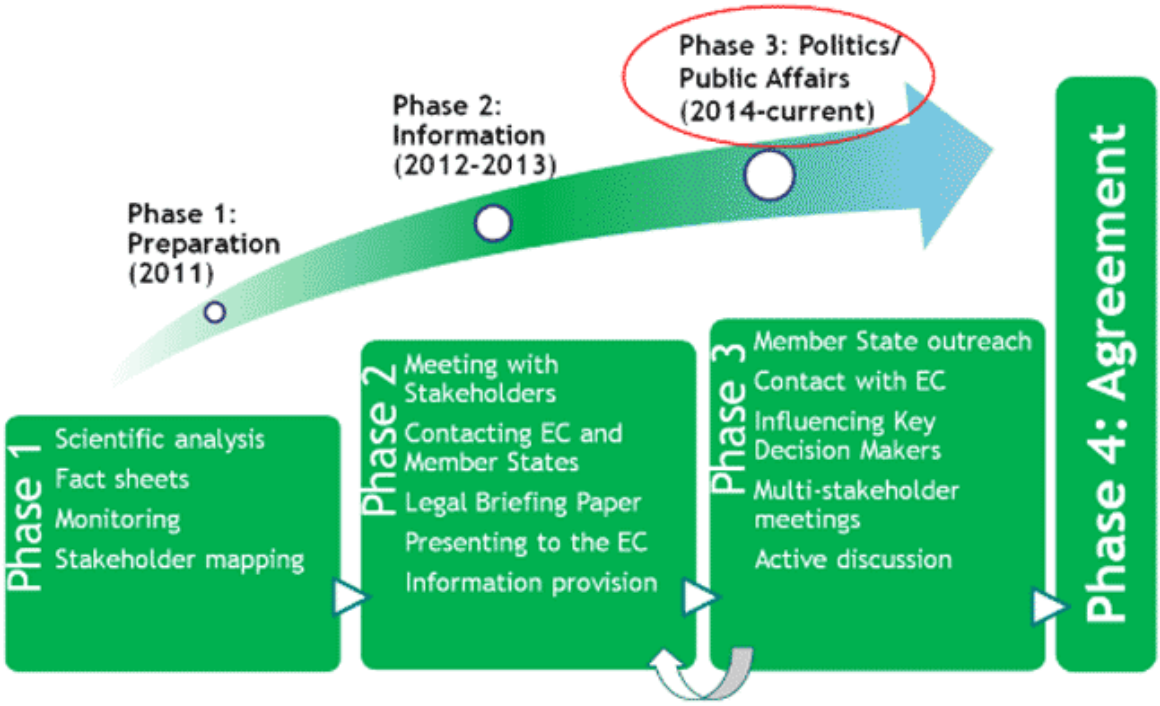
Indeed, it is important to note that both biotech SMEs and (semi-) public research institutes often play the role of technology suppliers for big multinationals. SweTree Technologies, for example, is engaged in the development of GM trees and claims to have applied for 75 patents in that field. Some of these products have already been licensed to BASF, and SweTree Technologies claims to collaborate with the corporation in several areas.[42]

Transparency register generates confusing and incorrect data on NBT Platform

In the EU Transparency Register, the NBT Platform claims that its lobby expenses total a mere €50,000-99,999 per year. This figure is not very meaningful, since every entity can invent its own way to calculate lobby expenses when signing up to the register. As the Platform's overall budget is not disclosed, lobby costs might in fact be much larger. Furthermore, the NBT Platform entry reports only a 0.5 FTE workload dedicated to the wide range of lobby activities falling under the scope of the register.[35] Schuttelaar & Partners Director Edwin Hecker is named as chair of the Platform, and the number of lobbyists with permanent accreditation to the European Parliament is registered as zero. However, in Schuttelaar & Partners' own entry to the EU Transparency Register, Hecker is mentioned as one of ten company employees holding a permanent accreditation pass to the European Parliament.

4. Multi-phased lobby campaign against EU GMO regulation

The NBT Platform's website clearly delineates the four phases of its campaign to give the death blow to GMO regulation for new GM products.[43]



Following the creation of the NBT Platform in the first phase, the second phase in the industry's lobby campaign to the European Commission was characterised by repeated efforts to showcase the new techniques and their claimed benefits, as well as the provision of technical and legal arguments for why they should go unregulated.

In the spring of 2012 for example, Schuttelaar & Partners teamed up to chair two meetings presenting new GM techniques to staff from DG SANCO, DG Trade, and DG Research and Innovation.[44] [45] Dow presented Zinc Finger Nuclease (ZFN) technology; Rijk Zwaan introduced agroinfiltration and reverse breeding; Bayer/Nunhems explained cisgenics; KeyGene made a pitch for ODM; and VIB put forward grafting on GM root stock. Syngenta and Inova Fruit were also present at the meetings.

In addition, a legal argumentation as to why the EU should not regulate ODM and cisgenics techniques in particular was presented by Wageningen University plant researcher Henk Schouten, who was also wearing his hat as lobbyist for Inova Fruit.[46] Inova Fruit, owned by large Dutch and Flemish fruit traders, contracted the private arm of Wageningen University to develop cisgenic apple varieties.[47] [48] Both Wageningen University and Inova Fruit clearly have commercial interests in getting cisgenesis deregulated. This shows the involvement of Wageningen University in private interest lobbying, despite its public denial of this kind of activity. (See case study *'Of apples and potatoes: the Dutch lobby for the deregulation of cisgenesis'*).

In May 2013, the NBT Platform presented the Commission with its pièce de résistance: the industry's own 'legal interpretation' of the regulatory status of new GM techniques.[53]

This was based on a sort of questionnaire consisting of seven main questions (and many subquestions) that, it is explained, must all be answered in the affirmative in order for a product to be regulated as a GMO. This methodology was carefully designed to ensure the desired outcome: that all of the new GM techniques in question should be unregulated, and by extension untested and unlabeled.[54]

1. Is it an organism?;
2. Is it non-human?;
3. Has the genetic material been altered (by 20bp or more) vis-à-vis the starting (parental plant) genetic material?;
4. The genetic alteration does not (and cannot) occur naturally (by mating and/or natural recombination)?;
5. Does the genetic modification occur at least through the use of the techniques listed in Annex I A part 1 of the Directive?;
6. Is the genetic modification not among the techniques listed in Annex I A part 2?;
7. Is the genetic modification not among the techniques/methods listed in Annex I B?

*Source: NBT Platform website

Question 3 and 4 aim to twist the definition of a GMO in EU Directive 2001/18, which is "...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". Using industry's methodology, most of the new techniques would escape regulation as they can provide a negative answer to one of these two questions. The Platform analysis also argues that some of the new GM techniques are simply a variation of mutagenesis (a technique that had long been in use when Directive 2001/18 was developed and that was explicitly excluded from its scope).[55] Furthermore, the industry approach aims to undermine the process-based nature of the Directive, as described earlier.

The arguments put forward by the NBT Platform are at the core of industry's rationale for the deregulation of new GM. These points, or variations on them, can also be found in lobby documents produced by the European Seed Association (ESA), the European Plant Science Organisation (EPSO), the pesticide lobby group Croplife International and the Flemish biotech research institute VIB.

Trade concerns (1): avoiding disruptions at all costs

In lobbying the Commission, DG Trade was not left out. In a first meeting in March 2012, Schuttelaar & Partners raised their clients' concerns about "the legislative uncertainty" for new GM techniques, and added that in this field "the EU occupies the second place in the world for patent applications, with the UK and the Netherlands contributing most significantly".[49] In late May 2012, Schuttelaar & Partners staged a second larger meeting, attended by DG SANCO, DG Trade, and "NBT Platform members" Dow Agrosciences, VIB, KeyGene, Syngenta, Bayer CropScience, Rothamsted Research, Rijk Zwaan, and Wageningen University.[50] Their message did not fall upon deaf ears. After the first meeting, a DG Trade official concluded that his DG would "have to ensure that any measure/solution proposed will not result in trade disruptions". And furthermore, he reported: "I was reassured by my SANCO counterparts that the trade angle will be taken into account when deciding on the Commission's line to take".[51] The European Seed Association announced to DG SANCO that it wanted new GM techniques deregulated, and specifically attacked the EU traceability and labelling requirements for their "potential to hamper free trade".[52]

The pro-deregulation interpretation of the scope of Europe's GM laws has been met with wide-ranging criticism. Counterarguments have been provided by German federal agencies (for example the opinion by Professor Tade Matthias Spranger for BfN, the German Federal Agency of Nature Conservation); a legal analysis by Professor Ludwig Krämer as commissioned by German civil society; and assessments by Greenpeace, farming and other environmental groups.

Similarly, industry's attempt to have new GM declared safe by design and therefore exempt from regulatory risk assessment has been countered by the Austrian Environmental Agency and various non-governmental organisations.

The legal case that new GM techniques should be covered by the current regulations is, in fact, crystal clear.

The central purpose of Directive 2001/18 on the deliberate release of GMOs is to protect human health and the environment from the release of genetically modified organisms. The Directive clearly provides for the advent of new GM techniques, which rely upon in vitro methods to directly modify genomes. These are the very type of techniques that EU law covers with its process-based approach (where the technique used decides if the regulations apply). That process-based regulation and the precautionary approach that lies at the heart of the directive are justified because of the unintended and unexpected effects of both GM 1.0 and GM 2.0 techniques. Techniques that have been developed since 2001 (or that didn't have any commercial application prior to 2001) cannot be regarded, as industry argues, the same as traditional mutagenesis techniques that were exempted on the grounds of a claimed 'history of safe use' when the EU regulations were introduced.

The key arguments from industry, and counter-arguments are summarised in the following table:

Table: Key industry arguments for the deregulation of new GM techniques

Industry argument[56]	Response[57]
1. "New GM is just like traditional plant breeding." Products from new GM are just like traditionally bred plants since "no foreign DNA is used". Industry seeks to reframe the legal interpretation of a GMO in this way, because many of the new techniques do not necessarily use DNA from another species, or use genetic material other than DNA.	In EU law, a GMO does not need to contain foreign DNA to qualify as a GMO. The Directive refers to "an organism …in which genetic material has been altered in a way that does not occur naturally by mating and/or natural recombination". The new techniques directly modify an organism's genetic material, without involving mating, and are therefore genetic engineering. In addition, the Directive also qualifies the introduction of other types of genetic material than DNA as GM.
2. "Just because a GM technique is used does not mean that the product is legally a GMO." If there is no GM material present in the final product, it should not be treated as a GMO. This is an attack on the process-based (technique-based) nature of the Directive, and would mean that products of several methods that do involve GM would be exempt.	The EU has recognised that the GM technique used to change an organisms does matter. It's the genetic engineering process that can lead to unintentional alterations of the genetic material, giving rise to concerns regarding food and environmental safety. These concerns remain even if the genetic engineering agent is subsequently removed.
3. "Gene editing techniques are a form of mutagenesis." Mutagenesis is excluded from the scope of the Directive, as it was assumed to have a 'history of safe use'.	New gene editing techniques are different and have no ''history off safe use''. They are different from the mutagenesis techniques (chemical and radiation) referred to in the Directive.

Industry argument	Response
4. "New GM is ''safe by design''." The claim is that the genetic interventions are precise and targeted and therefore safe. This is reflected by the terms used: gene or genome 'editing'.	New GM techniques can have multiple unintended and unexpected results. New GM methods pose very similar types of risks as GM 1.0, and should be regulated at minimum in the same way as existing GMOs in order to protect the environment and public health. Precision in changing the genetic makeup of an organism does not equate safety if you do not fully understand the impacts.
5. "Detection is impossible." Industry claims that detection methods will not be able to tell the difference between a new GM and a traditionally-bred product.	Detection methods are evolving, as are genetic engineering techniques. While distinguishing some new GM products from non-GM products may currently be difficult, this is very likely to change in the future.
6. "Application of the precautionary principle should be reconsidered." Industry claims that since there is less uncertainty related to new gene editing techniques than with mutagenesis using radiation or chemical mutagens, and since the precautionary principle is about uncertainty, it should not be applied to new GM techniques.	Precautionary principle should be respected. The precautionary principle and the process-orientated approach to risk assessment as established under EU law can only be implemented if the new methods are covered by the Directive.

5. Last phase lobbying

The third phase of the industry campaign, indicated in the graph by 'Politics/Public Affairs' (read: 'Lobby'), kicked in with a socalled 'multi-stakeholder meeting' held on 25 June 2014. 'The future of plant breeding techniques in the European Union'[58] was a co-production of the NBT Platform and the industry-driven European Technology Platform 'Plants for the Future'. However, the NBT Platform cast a narrow net when inviting 'stakeholders': on its list were the Member States' Competent Authorities, the Commission, and companies and their lobby associations (e.g. the European Seed Association, farming lobby Copa-Cogeca, and so forth). Absent were environmental and consumer NGOs, sustainable farming organisations, and the like.[59]

The industry campaign escalated during this phase, with dire predictions of economic collapse and job losses following the eventual regulation of new GM. According to the NBT Platform multi-stakeholder meeting report for example, industrial farming group Copa-Cogeca said that "overly strict" regulation would "increase unfair competition" for farmers. In turn, the European Plant Science Organisation (EPSO) insisted that the current legal uncertainty was causing "intelligence leakage" and destroying jobs, while another participant went as far as to warn that this ambiguity would lead to the "complete extinction" of a large part of the plant breeding sector in Europe![60]

By the start of 2015, the Commission appeared close to reaching a decision on new GM techniques, and things were starting to heat up.

In the spring, the German Government decided to take matters into its own hands. It determined that Cibus' ODM oilseed rape did not qualify as a GMO, so that field trialling could proceed with no regulation or monitoring. In response, the Commission quickly sent letters to Germany and all EU member states asking them to "await, as much as possible, the outcome of the Commission legal interpretation before authorising a deliberate release of organisms obtained with new plant breeding techniques" since "the deliberate release of products which are subject to the rules of the EU GMO legislation without appropriate prior authorisation, is illegal."[64] (See case study *'Canadian company railroads EU decision making on new GM'*).

But Cibus also informed the Commission that as its product was already being grown in the US, "the harvested material is used like any other crop and likely entering the international commodity chain". According to the company, the possibility of this unauthorised GM oilseed rape being imported into the EU could therefore not be excluded.[65]

Trade concerns (2): TTIP kicks in

Another line of argument pursued by the NBT Platform is the comparison of how new GM techniques are regulated – or not – in other parts of the world, cumulating in the suggestion that a stronger level of regulation in the EU will create trade barriers.

In the context of TTIP, the way the US deals with the new techniques is of particular interest. For example, US-based multinational Dow informed DG SANCO in 2013 of the decision by the US Department of Agriculture (USDA) to not regulate Dow's ZFN-1 maize.[61] The Commission later reflected however that the US Food and Drug Administration (FDA) "remains rather vague" on the issue.[62] It should be noted that the US hardly regulates GMOs as such. There are no formal data requirements when it comes to safety testing, and biotech companies voluntarily provide whatever information they please.

Emails released by the Commission provide evidence that the (de-)regulation of new GM techniques was indeed discussed in a March 2014 TTIP-related meeting in Washington. Despite repeated claims at the time by the Commission that "GM is not on the table", US and EU authorities sat together with seed industry lobby groups from both sides of the Atlantic (including the European Seed Association).[63]

Following the May 2014 elections, a new Commissioner in charge of DG SANTE (previously called SANCO) was installed, the Lithuanian Vytenis Andriukaitis.[66] The NBT Platform set the necessary liaison efforts into motion, and set up a meeting that took place in July 2015. The Platform also shifted focus to liaise and gather information from EU member states, and sought a meeting with the Commission (DGs SANTE, AGRI and Trade) to report back on these contacts.[67]

Furthermore, at two occasions in 2015, GM developers got assistance from certain member states that have also been peddling a pro-deregulation agenda with Brussels. In May 2015, a 'non-paper' authored by Germany, the UK, Ireland and Spain argued for the deregulation of the ODM technique in particular, using the same arguments as put forth by industry to argue that "ODM is a variation of mutagenesis".[68]

In September, the German food safety agency BVL, in a joint exercise with its UK and Irish colleagues, sent an interpretation of the definition of a GMO in Directive 2001/18 to the Commission.[69] This document precisely echoes the industry discourse that a product should only be regulated under EU GMO laws if it is produced by a GM process and if the result is a product that could not have been achieved in a 'natural' way.

Flemish biotechnology institute (VIB) and EASAC join the chorus

In this last phase, corporate-backed research institutes like the Flemish VIB also stepped up their efforts in order to defend their commercial interests. On 5 June 2015, the VIB met with the Commission to discuss a number of new techniques.[70][71] Although the list has not been disclosed following freedom of information requests, according to the VIB "... the examples given represent concrete business opportunities and vulnerable information from the viewpoint of competition". It appears likely from the Commission response and a related email exchange on the topic that the VIB is eyeing cisgenesis and certain gene editing techniques.[72][73] VIB has an obvious commercial interest in the deregulation of cisgenesis, after having put its money on turning the failed Dutch cisgenic potato into a Belgian specialty: a blight-resistant Bintje, a well known potato variety widely used for the country's famous fries.[74]

Moreover, in a remarkable statement addressed to the Commission in July 2015, the European Academies Science Advisory Council (EASAC), also backed industry's views.[75] Their political demands dovetail with those of industry: GMOs should be allowed to escape regulation "when they do not contain foreign DNA", that GM products should be regulated only by trait and not technique, and that the use of the precautionary principle in GM regulation should be reconsidered. The statement is based on the conclusions of an earlier EASAC report, 'Planting the Future'. This report was composed by a working group of experts "acting in individual capacity, nominated by member academies of EASAC".[76]

Meanwhile, in the European Parliament, some MEPs unsuccessfully demanded a formal say in the process. Others, including Jan Huitema (Liberals) and Anthea McIntyre (Conservatives), authored resolutions that included calls for the deregulation of new GM techniques. On 1 December 2015, a hearing took place in the European Parliament Agriculture Committee. Edwin Hecker, a NBT Platform lobbyist and an employee of Schuttelaar & Partners (although the latter was not disclosed), presented industry's views, again overstating the role of SMEs.[77]

Surprisingly, only one week later the NBT Platform was deleted from Schuttelaar & Partners' list of clients in the register. However the information in the NBT Platform's entry and on its website remains unchanged. (See box *'Does the NBT Platform still exist?'*).

Does the NBT Platform still exist?

Schuttelaar & Partners made some remarkable changes to their registry entry on 7 December 2015. The NBT Platform has been deleted as a client from the lobby group's entry. This is contradictory, as the NBT Platform's entry is unchanged and still lists Mr. Hecker as its chair.[78] In line with this change, the Commission's legal interpretation of Directive 2001/18 for the new GM techniques has been deleted from the list of EU initiatives followed by the company.

In addition, the company's overall lobby-related expenses have been reduced tenfold: from €100,000-500,000 down to €50,000-99,000.[79] The consultancy now declares just a 0.8 FTE workload for lobbying activities. This is at odds for instance with the fact that ten employees currently hold lobby passes for the European Parliament.[80]

6. The Commission's interpretation: Whose interests will prevail?

All invested parties are now awaiting the Commission's decision, to be presented in March 2016. Will the NBT Platform be celebrating victory after achieving its 'Phase 4: Agreement' goal? Or will concerned governments, NGOs, and sustainable farming organisations be relieved that the new GM technologies will be subject to the existing hard-won regulation?

Maybe neither. DG SANTE has already publicly stated that "some will be pleased, others disappointed",[81] indicating that at least one, perhaps more, but not all of the new techniques will escape regulation as a result of the Commission decision. If true this would – no matter how many techniques are concerned – be a serious attack on food and environmental safety, consumer choice and transparency in the food chain, as well as enhancing corporate concentration in the seed sector through patents.

As Brussels itself realises, the Commission release is probably just the beginning – and not the resolution – of this contentious issue. In all likelihood, it will be the European Court of Justice that ultimately determines the regulatory fate of new GM techniques. The court case brought by environmental and farming organisations against Cibus' ODM oilseed rape will therefore be of great importance.

In the meantime, neither the biotech industry nor its financiers are likely to have the certainty they have been striving for. Furthermore, other actors may still come into play. Food distributors may demand direct liability for new GM products to those who put them on the market. And parliaments may insist on the labelling of new GM products, like has happened in the Netherlands. The TTIP negotiations, on the other hand, may become a force against a proper regulation of GM 2.0. Environmental and sustainable farming groups will have to remain on high alert.

Notes

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3. Corporate Europe Observatory and Inf'OGM. TTIP: released emails show biotech, seeds on the trade talks table. 2 July 2015. http://corporateeurope.org/food-and-agriculture/2015/07/ttip-released-emails-show-biotech-seeds-trade-talks-table
4. The Working Group was made up of two experts nominated from each member state. Its final report was completed in 2012, but was never officially published.
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6. Testbiotech. Gene-editing and plants & animals used in food production: some technical, socio-economic and legal aspects. Backgrounder for Hearing on "New Techniques for Plant Breeding" in the EP Agriculture Committee. 1 December 2015. http://www.testbiotech.org/sites/default/files/Legal%20and%20technical%20aspects%20genome%20editing_Testbiotech_.pdf
7. Waltz, Emily. Tiptoeing around Transgenics. In: Nature Biotechnology, volume 30, number 3. March 2012.
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41. VIB website. As accessed 21 December 2015. http://www.vib.be/nl/over-vib/organisatie/Paginas/Algemene-vergadering.aspx

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50. DG Trade. Report from meeting with NBT Platform. 07 June 2012. Obtained through Freedom of Information request by CEO.

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52. European Seed Association (ESA). Position paper. Promoting and Enabling Innovation in Plant Breeding. February 2014. Obtained through Freedom of Information request by CEO.

53. NBT Platform. Legal Briefing Paper. The regulatory status of plants resulting from New Breeding Technologies. Version of 28 May 2013. Obtained through Freedom of Information request by CEO.

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55. The Directive 2001/18 (Annex 1B) lists two techniques – cell fusion and mutagenesis – for which an exemption has been granted, and that are therefore excluded from its scope. As these two techniques predated the Directive by many years, EU authorities assumed there was a 'history of safe use'.

56. The following documents exemplify the pro-deregulation arguments. Each uses one or more of the points listed in the table.
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    - European Seed Association. Regulatory approaches to modern plant breeding - the case of mutagenesis and new gene editing technologies. 20 July 2015. https://www.euroseeds.eu/system/files/publications/files/esa_15.0543_0.pdf
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    - Spranger TM. Legal Analysis of the applicability of Directive 2001/18/EC on genome editing technologies. Commissioned by the German Federal Agency for Nature Conservation. October 2015. http://bfn.de/fileadmin/BfN/agrogentechnik/Dokumente/Legal_analysis_of_genome_editing_technologies.pdf
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61. Dow Agrosciences and DG SANCO/JRC. Emails April 2012 and July 2013. Obtained through Freedom of Information request by CEO.

62. DG SANCO. Internal email. 8 July 2013. Obtained through Freedom of Information request by CEO.

63. Corporate Europe Observatory and Inf'OGM. TTIP: released emails show biotech, seeds on the trade talks table. 2 July 2015. http://corporateeurope.org/food-and-agriculture/2015/07/ttip-released-emails-show-biotech-seeds-trade-talks-table

64. European Commission. Letter to Competent Authorities. 5 June 2015. Obtained through Freedom of Information request by CEO.

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67. NBT Platform. Email to Mr Ladislav Miko (DG SANTE). 26 February 2015. Obtained through Freedom of Information request by CEO. NBT Platform. Email to DG Trade. 18 May 2015. Obtained through Freedom of Information request by CEO.

68. According to Agrafacts, the non-paper was authored by German, UK, Irish and Spanish authorities. Non-paper on the regulatory status of plants generated by oligonucleotide-directed mutagenesis (ODM). 21 May 2015. Obtained through Freedom of Information request by CEO.

69. BVL. Legal interpretation to DG SANTE. 28 September 2015. Obtained through Freedom of Information request by CEO.

70. DG SANTE. Reply to Vlaams Instituut voor Biotechnologie (VIB). 9 July 2015. Obtained through Freedom of Information request by CEO. (doc 24 a2d3).

71. Vlaams Instituut voor Biotechnologie (VIB). Letter to Mr Ladislav Miko (DG SANTE). 10 June 2015. Obtained through Freedom of Information request by CEO.

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77. European Parliament Committee on Agriculture. Hearing on "New Techniques for Plant Breeding". 1 December 2015.https://polcms.secure.europarl.europa.eu/cmsdata/upload/d35d2641-ab77-4904-8a55-14849215d6f0/Draft%20programme.pdf

78. Furthermore, Schuttelaar & Partners now lists only one client (Grodan, a supplier to the horticulture sector). This is in sharp contrast to the lobby firm's own website, where 11 clients from the food and biotech sectors are listed as examples of "current and recent clients". Schuttelaar & Partners website. As accessed 13 December 2015. http://www.schuttelaar-partners.com/clients

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Case Study 1

Of apples and potatoes: the Dutch lobby for the deregulation of cisgenesis

The voice of the Dutch Government has been loud and clear in Brussels on the issue of cisgenic plants. The Dutch have waged a sustained campaign to have new GM techniques – and in particular cisgenesis – excluded from EU GMO regulations. Several Dutch ministries, the Dutch Parliament, the Dutch Permanent Representation in Brussels, and Dutch MEPs have energetically pursued this goal.

The Dutch GM potato

So why is the Netherlands so focused on the regulatory status of cisgenesis? In short, the Dutch are hoping that cisgenic genetic engineering can make the Dutch plant breeding sector more competitive. The Netherlands is known for its considerable stake in the seed industry. The Dutch potato sector for example accounts for 60 per cent of global exports in seed potatoes.[1] However, fears have been expressed in The Hague that the sector could lose its standing if competitors from other countries are able to use genetic modification, which consumer rejection has ruled out in the Netherlands.[2]

For this reason, the Dutch Government committed public research funding in 2005 to the development of a 'national GM potato'. Ten million euro was made available to Wageningen University to develop a GM potato that is resistant to late blight (Phytophthora infestans). The project – 'Durable Resistance to Phytophthora' (or DuRPh, which means 'dare' in Dutch) – 'stacks' three to five blight-resistant genes from wild varieties of potatoes, and then inserts them into commercial potato varieties.

Dutch Government policy is to cap public science funding at 50 per cent of a research project, requiring matching funding from the private sector. Yet in this case the Dutch potato sector refused to invest in the project, and the exceptional decision was taken to entirely finance the R&D of the GM cisgenic potato from public science coffers. A sizeable one-tenth of the DuRPh budget – one million euro – was allocated to communication with stakeholders and the public in order to overcome the anticipated resistance to the project.

However, there was an additional obstacle for project sponsors: European GM laws, which play a crucial role in facilitating consumer choice. If classified and labeled as a GMO, rejection by consumers and the potato processing industry would likely stymie the commercial success of the project. Having cisgenesis excluded from GM laws thus became a key objective for the Dutch Government.

Convincing Dutch Government and Parliament

In the political arena, the first step was to convince Dutch political parties that cisgenic potatoes should be treated differently from 'traditional' GMOs. The Protestant Orthodox party ChristenUnie, which has a history of critical positioning on GM, seemed like a good starting point. Not only was DuRPh researcher Henk Schouten a party insider, but ChristenUnie was entering a government coalition for the first time in 2007. At a parliamentary roundtable on biotechnology that year organised by a ChristenUnie MP,Schouten represented the private arm of Wageningen University – Plant Research International – and repeated that cisgenesis "is closer to nature and the order of [God's] creation".[11]

Cisgenesis vs transgenesis: is the debate scientific or semantic?

The term 'cisgenesis' refers to the insertion of genes from the same or closely related species into a recipient plant, in contrast with transgenesis, whereby genes from another species are introduced. Wageningen University plant scientists Evert Jacobsen and Henk Schouten are considered the 'fathers' of cisgenesis; Schouten coined the term in 1999.[3]

Schouten and Jacobsen made their case for cisgenesis in the *Nature Biotechnology* journal in 2006, stating that "cisgenic plants are fundamentally different from transgenic plants", and that they should be "handled at the regulatory level like traditionally bred plants".[4] On a dedicated website run by Schouten and Jacobsen and supported by Wageningen University[5] cisgenesis is described as "a next step in classical breeding for improving crops". A 'white paper' on the website puts forth the case for deregulating cisgenesis, with the key argument that "plants without foreign DNA should not be regarded as GMOs". Despite all of these statements however, the Wageningen researchers clearly acknowledge that cisgenesis is genetic modification, both on this website and in public debates.[6]

Cisgenesis as practiced in the DuRPh project involves the use of a standard genetic engineering technique.[7] In fact, two-thirds of the DuRPh potatoes contained marker genes of bacterial origin, and are thus technically transgenic. (The researchers claim that these genes will not be present in the final product.)[8]

The article accordingly sparked a lively debate in *Nature Biotechnology*. Two groups of scientists (one of them comprising Dutch plant breeding experts) criticised Schouten and Jacobsen's argumentation, maintaining that cisgenics cannot be regarded as equivalent to traditionally breeding in terms of food and environmental safety.[9]

Independent Science News added to the discussion, saying "while categorizing transgenes according to their origins may have merit, changes to risk assessment and regulations need to be based on scientific data not semantics".[10] They looked at actual experimental data that do not seem to support claims made by the Wageningen researchers, for instance that products resulting from cisgenesis are equivalent to those resulting from traditional breeding.

Nonetheless, the director of the Wageningen Plant Sciences Group, Ernst van den Ende, later denied that the University had undertaken any political lobbying: "We deliver facts and insights. We have nothing to do with decision making."[12] He claimed that if university researchers communicate favourably about cisgenesis, they do so "in their personal capacity".

So let's have a look at the capacity in which Schouten makes the case that cisgenics should be excluded from GM laws in meetings with EU decision makers. While Wageningen University is not an official member of industry's EU lobby vehicle, the New Breeding Techniques (NBT) Platform, Schouten represents the Dutch fruit breeding company Inova Fruit, a client of Wageningen's Plant Research International, in that Platform. Inova Fruit, which is owned by several large fruit auctioneers including The Greenery, contracted Wageningen University to develop a cisgenic apple variety.[13] In this context, Schouten is listed as an inventor in a patent application by Inova Fruit.[14] This dual role leads to situations where Schouten wears two hats: at an important meeting set up by the NBT Platform in 2012, Schouten attended both as a Wageningen University researcher and as a representative of Inova Fruit.

This situation illuminates the active role played by Wageningen University in the lobby for the deregulation of cisgenesis. Wageningen's political priorities appear to be focused on the interests of its private clients, as well on potential future spin-offs and the patent portfolio of the university.

The business case for cisgenic crops

Cisgenic crops have economic appeal in that a specific new trait can be added to an existing variety that has a solid reputation and market position, like Bintje potatoes or Gala apples.[15] The novelty of the new trait and/or the resulting variety can then be patented without having to change the original variety name. Growers can then be charged higher prices due to the patents. Patents undermine the rights of plant breeders and farmers to produce new varieties and seeds, and thereby jeopardise agrobiodiversity.

The certitude promoted by industry and Wageningen about the safety of cisgenics did not however go undisputed. When the Dutch RIKILT Institute of Food Safety, which is linked to Wageningen University, was asked in 2010 to assess the risks of cisgenics, it concluded that "there is, from a food and feed safety perspective, no scientific basis for a general reduction of requirements for cisgenic crop plant varieties".[16] IKILT also concluded that the definition of cisgenics is ambiguous in terms of food safety, "as it may not exclude wild relatives that are not part of the human diet so far and that can only be crossed under laboratory conditions". If that is the case, there is no "history of safe use", and the safety of the newly introduced nucleotide sequences and protein(s) would have to be assessed.[17]

In 2012, the European Food Safety Authority (EFSA) issued an opinion on the risks associated with cisgenics.[18] The only external expert invited to give his view to the EFSA working group developing this opinion was Evert Jacobsen of the Wageningen DuRPh team. The working group concluded that "similar hazards can be associated with cisgenic and conventionally bred plants". However, it was added that the possibility of unintended changes still mandated a case-by-case assessment.

In the meantime, Schouten had successfully convinced the ChristenUnie that cisgenesis would not constitute an interference in God's creation. Following the EFSA opinion, a ChristenUnie parliamentarian stated that cisgenesis is "not only safe, but also ethically responsible",[19] and tabled a resolution in the Dutch Parliament calling for the exclusion of cisgenesis from EU GMO laws.[20] The resolution cited EFSA's conclusion that the risks from the technique are comparable to those associated with conventional breeding. The other half of EFSA's conclusion however, calling for a case-by-case assessment, was left out of the resolution text. The resolution was voted in by a majority consisting of centre and right-wing liberal and conservative parties. Left- wing parties voted against the resolution.[21]

Push for cisgenic potatoes moves to Brussels

From this point on, the EFSA opinion became the Dutch Government's main argument in its push for the deregulation of cisgenics at the EU level. In late 2012, Dutch officials from the Ministry of Environment and the Permanent Representation in Brussels met with Ladislav Miko from the Directorate-General for Health and Food Safety (DG SANCO).[22] They conveyed the desire of Dutch researchers and industry "to have some or all new plant breeding techniques out of the scope of the GMO legislation", and welcomed the EFSA opinion on cisgenics.

Again the following year, both the Dutch Environment Minister[23] and the Ministry of Agriculture[24] urged the Commission to issue a decision on the new cisgenic techniques. In addition, the Dutch Secretary of State for the Environment told the media that cisgenic crops should go unlabelled, but that a traceability system could guarantee a cisgenic-free organic food sector.[25]

Around the same time, ChristenUnie MEP Peter van Dalen pushed the issue in a European Parliament report on horticulture. His political group inserted changes favouring a different approval process for cisgenic plants than for GMOs, "so as to recognise that cisgenesis is an accelerated form of conventional plant breeding".[26] The following year, van Dalen prodded the Commission about how and when it intended to act upon this horticulture report.[27]

The NBT Platform events meanwhile also prominently pushed the case of cisgenesis. (See article *'Biotech lobby's push for new GMOs to escape regulation'*). Schuttelaar & Partners - with offices in Brussels, The Hague and Wageningen - and the lobbyist in charge Edwin Hecker, a former official at the Dutch Ministry of Agriculture, seemed indeed well placed in that respect.

In the meantime, another project promoting a blight-resistant potato had been launched at Wageningen University in 2008. Developed in cooperation with an organic plant breeding institute, this 'Bioimpuls' potato was non-GM and focused on the organic sector. Yet when Wageningen researcher Richard Visser presented the DuRPh project at a December 2015 European Parliament hearing on "new plant breeding techniques", he failed to even mention this organic potato developed – within the same university – in parallel with the GM one but granted roughly four times fewer financial resources.[28]

Dutch potato to become Belgian fry?

The Dutch Government has clearly gone out of its way to push cisgenics, both in terms of funding and political lobbying. Thus it was an embarrassing defeat when the flagship GM potato – the project that was designed to secure the competitiveness of the Dutch potato industry – failed to attract sufficient industry investment to continue in the summer of 2015.

If cisgenesis were however to be exempted from EU GM laws and thus escape labelling, the situation could change quickly. A struggle can be expected between the Dutch Government and the Parliament: in 2014, the Parliament adopted a resolution demanding that cisgenic products be labelled even if excluded from GM regulation, in order to guarantee freedom of choice.[29] This is precisely what government officials and researchers set out to avoid when they began the campaign for the deregulation of cisgenesis. Consequently, if their deregulation lobby proves successful at the EU level, they will find themselves in a very awkward situation. Proposing to label a product that has just been exempted from the EU GM law will not be a popular move in Brussels, where the Netherlands holds the EU Presidency in the first half of 2016.

In the meantime, the Flemish biotechnology institute VIB has taken over the drive to commercialise the Dutch cisgenic blight resistant potato, aiming to develop a GM version of the Bintje potato that is much used for the famous Belgian fries.[30] The VIB has in turn become strikingly vocal with EU decision makers in the bid to have new GM techniques excluded from EU laws. "It is to be hoped", VIB states, "that the EU will not apply the stringent GMO legislation to the cisgenic blight-resistant potato, otherwise the cisgenic Bintje will face a long authorisation procedure". (See also *'Biotech lobby's push for new GMOs to espace regulation'*).

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Case Study 2

US company railroads EU decision-making on new GM

At least one developer of new GM crops – US-based Cibus – has attempted to bypass the European policy process by presenting policy makers with a fait accompli: decisions by individual Member States on the regulatory status of new techniques, as well as prematurely-launched trials of new GM crops.

Exchanges between Cibus and German regulators reveal the company's frustration about what it considers legal uncertainty over the regulatory status of one of the new techniques, Oligonucleotide-Directed Mutagenesis (ODM). "This evaluation", the company noted, "is prolonged, and until a final interpretation is provided the status of products derived with these techniques remain undecided."[1]

Divide and conquer

To break through this apparent impasse, Cibus adopted a strategy that could in effect force the hand of Brussels. The company approached individual Member States to have its first ODM product – a herbicide-resistant oil seed rape developed in partnership with Rotam CropSciences, a global pesticides company – deemed non-GM in their jurisdictions. In the words of a company representative, the authorities "responsible for GMO regulations in EU Member States are being contacted to evaluate how field trials with this material can proceed".[2]

Cibus is known to have approached at least six Member States.[3] This manoeuvring could, as one regulator noted to the Commission, create division within Europe as "interpretations by each individual Member State may lead to a situation where the interpretations in the Member States may differ from each other".[4]

In 2011, the company made formal enquiries with the UK regulator DEFRA, and subsequently approached the Swedish Gene Technology Advisory Board. To the latter, Cibus expressed interest in "the unconfined release of our herbicide [sic] spring oilseed rape in Sweden".[5]

After reviewing the applications, the UK and Swedish regulators cautioned the company that although they did not consider ODM as meeting the legal definition of a GM technique, this determination was only relevant in their territory and the European Commission could take a different view.[6] [7]

Cibus made similar overtures to the Finnish Board of Gene Technology. In early 2014, the Board contacted Brussels for assistance, citing its "challenging position" of having to respond to developers in the absence of legal clarity.[8]

The Commission warned the Finnish regulator against preempting Brussels, stating: "This evaluation is complex and requires a thorough legal analysis by the Commission, which is currently ongoing and is addressing not only ODM, but also other New Plant Breeding Techniques."[9]

Finally, in 2014, the company approached the German Federal Agency for Consumer Protection and Food Safety (BVL) for a decision on whether the herbicide-resistant ODM rape was a GMO.

Cibus's backdoor strategy with the German regulator was led by Perseus, a consultancy specialising in "biotechnology regulatory challenges".[10] The application was shepherded by Perseus founder Patrick Rüdelsheim, who was previously the Global Head of Regulatory Affairs BioScience for GM seed companies Aventis CropScience, Bayer CropScience and the AgrEvo group.[11]

In initial communications between the German regulator and the company, Cibus was informed that the regulatory assessment "will not include any participation or active information of the public or involvement of other authorities".[12]

Ultimately, the German Consumer Protection and Food Safety Agency (BVL) decreed the technique to be non-GM[13] – a view that is not shared by all German government agencies. A legal opinion commissioned by

the German Federal Agency for Nature Conservation came to the opposite conclusion. This second opinion affirmed ODM as a GM technique, and concluded that the regulatory exclusions cited by the Consumer Protection Agency as a basis for considering ODM as non-GM were never intended to cover novel genetic engineering techniques.[14]

However, in response to Germany's announcement that it would allow Cibus to carry out field trials in an entirely unregulated fashion, the Commission quickly sent letters to Germany as well as all of the other EU member states asking them to "await, as much as possible, the outcome of the Commission legal interpretation before authorising a deliberate release of organisms obtained with new plant breeding techniques" since "the deliberate release of products which are subject to the rules of the EU GMO legislation without appropriate prior authorisation, is illegal."[15]

Perseus wrote angrily to DG SANTE, incensed that the Commission had written to the German Government requesting that any outdoor trialling be suspended at least until the Commission had issued its guidance – a move that Perseus was apparently not aware of until the Commission letter was released by German NGO, Testbiotech. Perseus had met with the Commission earlier that month, and the company suggests, received an entirely different message from officials: advice on how to proceed with trialling its ODM rape without making waves: "During our meeting it was suggested that Cibus should discuss best practices with the relevant CA [competent authorities, ed.] and that it would be important to consider how to create a serene atmosphere during the evaluation process. The recent letter [from the Commission, ed.] seems to go beyond these suggestions".[16]

A coalition of 45 German NGOs brought the German Federal Agency's (BVL) decision to court. Due to these ongoing court proceedings, BVL informed the Commission on 29 July 2015 that its decision to allow the field trial had been suspended.[17]

Cibus ODM rape already in the supply chain?

Not content with attempting to railroad Europe into deregulating ODM, Cibus is also claiming a fait accompli with respect to Europe's food supply chain. In an early 2015 letter to the European Commission, the company stated that its novel herbicide resistant oil seed rape, which the company has dubbed Rapid Trait Development System (RTDS™), was "likely entering the international commodity chain" and that "it can therefore not be excluded that commodities with RTDS products are imported in the EU".[18]

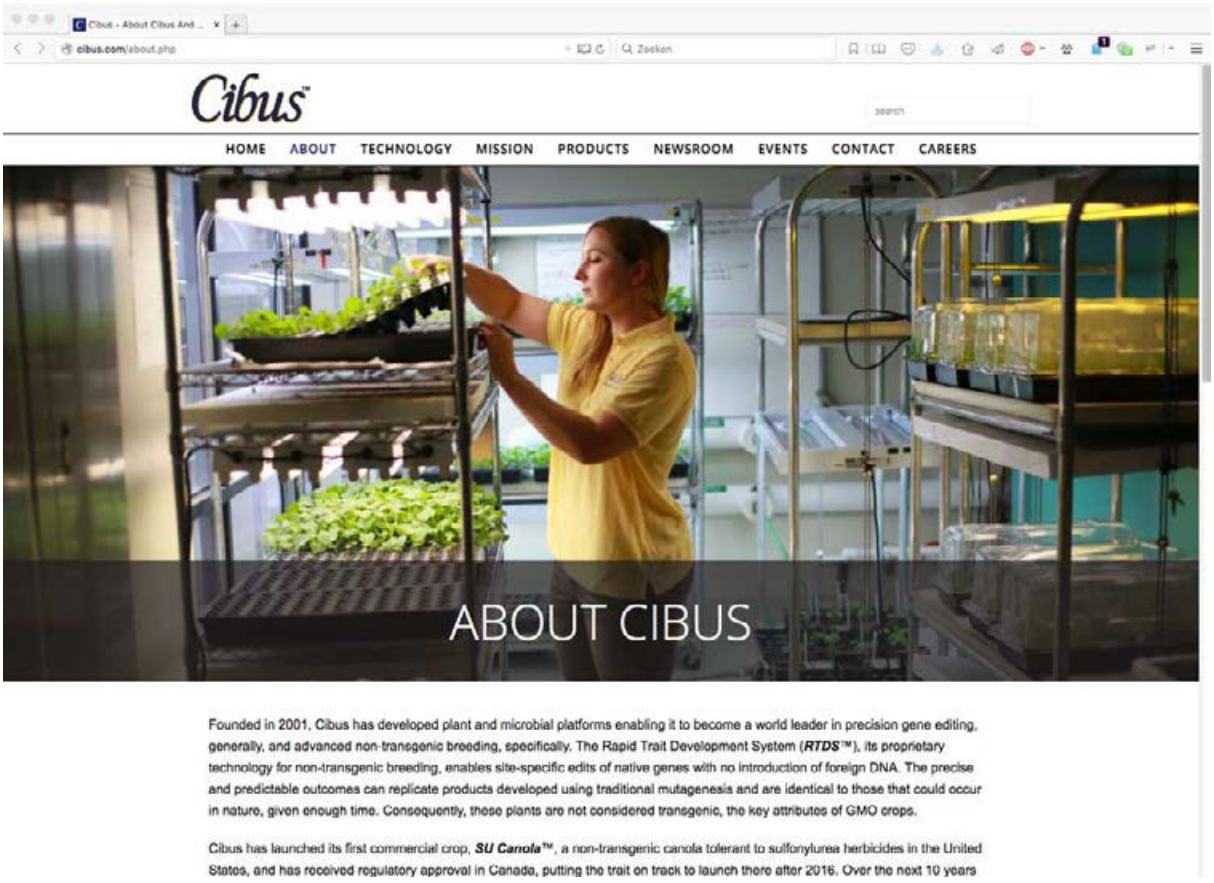
Yet while the extent to which the ODM rape has entered the supply chain is unclear, very little is likely to have reached Europe – and certainly much less than the company's communication with the Commission might suggest. Despite Cibus's expectations of "rapid market expansion in North America",[19] the commercial rollout of its new GM oilseed rape has experienced several delays. Following earlier predictions of a commercial release in the US in 2013, Cibus later foresaw a relatively modest planting of 40,000-50,000 acres in 2014 – around 3% of the total US canola acreage that year. The actual scale of last season's production has yet to be officially confirmed by the company.[20] Meanwhile, it is now believed that there may not be a limited release of ODM oilseed rape seed on the Canadian market until 2017 or even 2018.[21]

Fake it till you make it

Since at least 2007, Cibus has repeatedly let it be understood by North American agricultural sectors that its ODM technology is not GM under European law[22]– long before Europe has even come to a formal and final decision on the matter. The company has been recruiting North American partners to develop new food crops using the technique, and in a sales pitch that aims to build momentum, has been securing R&D joint ventures and public science funding on the basis of false assurances.

ODM as non-GM: a self-serving definition

Cibus's point that ODM will not legally qualify as GM in the EU has no clear basis in European law. The company conveniently ignores the EU's broad legal definition of GMOs in its claim that an organism is only genetically modified if foreign DNA is introduced – that is, that only transgenic genetic modification is covered by EU regulations: "We all understand GMO to be transgenic. And as such, we're not GMO."[23] The company's website similarly promises that its products are "free of the market resistance and regulatory burden of products engineered using foreign genetic material."[24]



* Cibus website advertises ODM oilseed rape as non-GM

Four years ago, the company boldly stated: "We are very confident we won't have any issues at all in taking our technology into Europe as a non-GM technology."[25] This confidence appears to have been misplaced, as the German regulator's decision has proven highly controversial. Consumer protection and environmental NGOs, as well as other groups in the country, are calling the move a 'backdoor bid'[26] to get GMOs into German agricultural fields. The case looks set to go all the way to the European Court of Justice – not exactly the positive publicity or brand association the company has promised to investors.

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