Media briefing 21 April 2016

Commission fails to regulate new GMOs after intense US lobbying

The European Commission has shelved a legal opinion confirming that genetically modified organisms (GMOs) produced through gene-editing and other new techniques fall under EU GMO law, following pressure from the US government. A series of internal Commission documents obtained under freedom of information rules reveal intense lobbying by US representatives for the EU to disregard its GMO rules, which require safety testing and labelling.

The documents show that US pressure is focussed on potential barriers to trade from the application of EU GMO law. They suggest that the EU should ignore health and environmental safeguards on GMOs to pave the way for a transatlantic trade agreement. The next round of TTIP negotiations starts on 25 April 2016 in New York.

EU health commissioner Vytenis Andriukaitis meets US trade representative Michael Froman in the US in December 2015.

This briefing exposes lobbying by the US government during a crucial period, at the end of 2015, as revealed in pre-meeting briefings and correspondence released by the Commission (please find links to original sources in the table in the Annex).

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The Commission's directorate-general for health and food safety (DG SANTE) announced last year that it would publish a **legal opinion *"by end 2015"*** [Docs 44, 45] on whether or not GMOs created through a range of new techniques are classified as GMOs under existing EU law. The techniques are listed on the Commission website under the industry-coined heading *"New Breeding Techniques"*, or "NBTs", and include gene-editing techniques such as oligonucleotide directed mutagenesis (ODM) (see box below).

This announcement by the Commission triggered a series of lobby efforts, including by the GMO industry, NGOs and governments. Civil society organisations, including Greenpeace, met commissioner Andriukaitis and his cabinet on 28 September and 9 December.

In advance of a meeting with DG SANTE's deputy director-general Ladislav Miko, on 7 October 2015, **the US mission to the EU said "*it came to their attention*" that the Commission's legal opinion was going to classify the ODM gene-editing technique "*as a GM technique*".** The US mission warned DG SANTE that this would be "*another blow to agriculture and technology*", according to a Commission briefing [Doc 44].

Echoing this information, the European Seed Association (ESA) said in a position paper on 2 October 2015 that the Commission was going to apply *"a strict process based legal interpretation with more techniques qualified as leading to GMOs"* in order to limit its exposure to "*potential legal challenges (by NGOs)".* On ODM in particular, ESA stated that "*the Commission (in particular the Legal Service) appears to be leaning towards a more restrictive interpretation*" [Doc 7.3]. The paper was sent to DG SANTE on 8 October 2015 [Doc. 7.3] and to DG TRADE on 16 February 2016 [Doc AtD 2016-0861 Doct 5]. Members of ESA include US GMO companies Pioneer and Dow Seeds.

Both **the US mission and ESA said the Commission's legal opinion would be released on 19 November 2015** [Docs 44 and 7.3]. This was the date of a planned meeting of EU member state GMO experts, according to ESA [Doc 7.3].

In a preparatory briefing ahead of a meeting with the US mission, DG SANTE suggested that Arunas Vinciunas, head of cabinet for EU health commissioner Vytenis Andriukaitis, "*clarify that the conclusions will not be presented on November 19th, but later by the end of the year (no specific date has been fixed yet)*" [Doc 44]. The "*line to take*" on the content of the legal opinion, for this and other meetings, was that "*results cannot be anticipated*" [Docs 42, 44, 45, 47].

The fact that the Commission documents do not reveal any details about its legal opinion is not surprising. DG SANTE was acutely aware of freedom of information requests by NGOs. As one Commission document says: "*To be noted: (…) Corporate Europe Observatory (CEO), sent six requests for access to documents related to the issue of new breeding techniques in a period of a year time [sic] (end 2014 until today). (…) All the documents provided allowed the NGO to gather a good overview of the Commission's activities in the area of new breeding techniques*" [Doc 42].

Intense US lobbying

"New breeding techniques" were on the agenda of at least three meetings between DG SANTE and US representatives between 7 and 28 October 2015. Commissioner Andriukaitis and US representatives also met on 23 and 25 November 2015, although it is unclear whether new GMOs were discussed. However, new GMOs were on the agenda for the commissioner's visit to the US between 30 November and 4 December 2015, where he also met US trade representative Michael Froman.

On 3 November, the US mission also sent a letter to the Commission warning it of "*unjustified regulatory hurdles*" for "*New Breeding Techniques*". It also rather ominously said that **"*different regulatory approaches between governments to NBT classification would lead to potentially significant trade disruptions*"** [Doc 16].

All these meetings took place just when the Commission was expected to be putting the final touches to its legal opinion, announced for the end of 2015. In January 2016, following the flurry of meetings with US representatives, the Commission said the opinion would be completed in the "*first quarter of 2016*". We are now in the second quarter of 2016, but the Commission has given no further timeline.

US position guided by industry

US companies are heavily involved in gene-editing, including ODM. Cibus, a US company, has already brought a herbicide-resistant oilseed rape engineered through ODM to the US market. The so-called SU Canola was grown on 4,000 hectares in 2015. Cibus has tried to bypass the EU process by getting EU national authorities to classify ODM as non-GM. Dow Chemicals and DuPont, two US companies that recently merged into DowDuPont, also have a strong interest in gene-editing, as documented by their recent patent applications in the field.

The US government has a long record of backing GMO companies, which often turn to the US trade representative (USTR) for help with overseas markets. In 2014, an unnamed US trade official chaired a lobby meeting of US and EU GMO companies with the European Commission delegation in Washington [Doc 31]. More recently, GM soy producers asked the USTR to pressure the Commission to speed up the approval of Monsanto GM soybeans.

What is gene-editing?
Gene-editing covers a range of new laboratory techniques to modify the DNA of a living organism.
Most gene-editing techniques use enzymes to 'cut' parts of the genome. The genome then 'repairs' itself. The result is an insertion, replacement or removal of bits of DNA. Unintended DNA cuts or other gene alterations can also occur, with unknown consequences. These techniques include zinc finger nucleases (ZFN), transcription activator-like effector nucleases (TALENs) and the clustered regularly interspaced short palindromic repeat (CRISPR) systems.

Another gene-editing technique involves the introduction of short strands of synthetic DNA that triggers cells to modify their DNA to match the introduced fragments. This technique is oligonucleotide directed mutagenesis (ODM).

The gene-editing process is not well understood, especially in plants. It can result in negative effects on the environment, and human and animal health. As little is known about how these techniques actually work, it is difficult even to identify potential hazards.

TTIP a threat to EU standards
The USTR has complained that EU GMO policies "*restrict the importation and use of U.S. agricultural commodities derived from agricultural biotechnology*". He said: "*The United States continues to press the EU for fundamental improvements in its regulatory system with the goal of normalizing trade in agricultural products derived from modern biotechnology*."

The main objective of TTIP is to harmonise transatlantic rules in a range of areas – including food and consumer product safety and environmental protection. These rules vary widely between the EU and the US (see box below). **NGOs have warned that TTIP would not only stop further regulation, it would also stop proper application of current EU standards.**

Civil society organisations, small-scale farmers and the organic sector have called on the Commission to apply EU GMO law to all products of genetic engineering, including new breeding techniques.

GMO regulation – differences between the US and the EU

The EU has a set of GMO laws that require case-by-case risk assessment, detectability and labelling of GMOs. The term GMO is defined as any organism, with the exception of humans, *"in which the genetic material (DNA) has been altered in a way that does not occur naturally by mating or natural recombination"*. Gene-edited plants and animals should be covered by the law, according to recent legal opinions by EU legal experts Tade Spranger and Ludwig Krämer.

In the US, GMOs are not systematically tested and can even be placed on the market without any form of testing. Labelling is not required and the Food and Drug Administration (FDA) only recently rejected a "citizen petition" to require mandatory labelling. Gene-edited plants and animals are mostly unregulated. US regulators ruled that Cibus' SU Canola is exempt from regulation. US rules governing GMOs are currently under review.

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Annex

Documentation of meetings and correspondence

Date	Document	Document number
21 March 2014	Meeting with European and American Seed Associations	31
2 October 2015	ESA position paper attached to a letter from Assosementi to DG SANTE of 8 October, and a letter from ESA to DG TRADE of 16 February	7.3 AtD 2016-0861 Doct 5
7 October 2015	Meeting between DG SANTE and **US FDA** (Food and Drug Administration)	Mention in document 44 (also referred to in 16)
9 October 2015	Meeting between DG SANTE and German ministry for food and agriculture	42
23 October 2015	Meeting between Andriukaitis' head of cabinet and **US mission to the EU**	44
28 October 2015	Meeting between DG SANTE and **US mission to the EU**	38, 45
3 November 2015	Letter US Mission to the EU to DG SANTE	16
23 November 2015	Meeting between Andriukaitis and Anthony Gardner, **ambassador of the US to the EU**	
25 November 2015	Meeting between Andriukaitis and Donald Prater, Acting Director of **US FDA** (Food and Drug Administration)	
30 November – 4 December 2015	Official visit Andriukaitis to the US, including meetings with - Tom Vilsack, **US secretary for agriculture**, - Michael Froman, **US trade representative**, - Stephen Ostroff, acting **commissioner of the US FDA** (Food and Drug Administration)	47