

## **Revealed: The deal between the German Food Safety authority (BVL) and the biotech industry on CIBUS oilseed rape**

### Decision-making behind closed doors

**3 November 2015 / After conducting confidential talks, the US company, CIBUS, has reached an agreement with the German Federal Office of Consumer Protection and Food Safety (BVL), that its RTDS oilseed rape will not be subjected to regulation for genetically engineered plants. This can be concluded from exchange of emails made available to the Gen-ethical Network (GeN) in Germany. The email correspondence between the BVL and industry shows that there was an agreement from the very beginning to exclude any public participation. CIBUS oilseed rape is produced by using techniques often known collectively as genome editing. Civil society organisations are now demanding that EU regulations are applied to these plants in the same way that they are applied to genetically engineered organisms - and that they undergo risk assessment and labelling. They are further pressing for higher priority to be given to the protection of health and the environment as well as the right of the public to know about the decision-making process.**

“We are concerned that public was completely excluded from the decision-making process despite the far reaching implications this deal could have. This is about deciding what in future will be regarded as genetic engineering and what will just come on to the market with no risk assessment and labelling”, says Christof Potthof for GeN. “We are alarmed by the fact that both sides seem to be exchanging information in a rather informal way. It appears that there was a mutual interest in concluding the deal before the EU Commission had a chance to come up with its own assessment.”

The BVL published its decision at the beginning of February, even though the EU Commission was not expected to decide on the regulatory aspects of the techniques used to produce the CIBUS oilseed rape before the end of the year. Authorities of several EU Member States such as Finland, the Netherlands, Sweden and UK were already known to be supportive of the biotech industry and had already had agreed to the request from CIBUS. The US company seems to be very confident that the outcome will be favourable as it is already advertising its plants as being excluded from regulation for genetically engineered organisms. However, a recent legal dossier drawn up by Professor Dr Ludwig Kraemer, who is widely regarded to be one of the top experts in environmental law and EU policy, made it clear that RTDS technology and, consequently, CIBUS oilseed rape should be subjected to EU regulation. The same conclusion can be derived from a legal dossier recently published by the German Federal Agency for Nature Conservation.

Civil society organisations are warning that it will become a precedential case if genome editing methods are not regulated. “CIBUS and the German BVL are jointly attempting to avoid existing regulation. But economic interests cannot be a reason to set aside the very basic principles of EU law”, says Christoph Then for Testbiotech. “We need to set the right priorities, which are protection of health, the environment, transparency and traceability”.

The RTDS technique developed by CIBUS involves short sequences of synthetic DNA, so-called oligonucleotides, being inserted into the plant cells. According to CIBUS, the mechanisms which cause the plant cells to adapt its own DNA to the artificial templates is not known in detail. Publications show that side effects in the genome cannot be excluded with RTDS. The data sent by CIBUS to the German authority show that there were, in fact, significant changes in some plant components, which were not investigated any further but set aside as being without biological relevance.

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The email correspondence between German authority and industry: [www.testbiotech.org/node/1414](http://www.testbiotech.org/node/1414)

The decision of the German authority, February 2015: [www.testbiotech.org/node/1176](http://www.testbiotech.org/node/1176)

The Ludwig Kraemer legal dossier: [www.testbiotech.org/node/1342](http://www.testbiotech.org/node/1342)

The German Federal Agency for Nature Conservation legal dossier:

[http://bfm.de/fileadmin/BfN/agrogentech/Dokumente/Legal\\_analysis\\_of\\_genome\\_editing\\_technologies.pdf](http://bfm.de/fileadmin/BfN/agrogentech/Dokumente/Legal_analysis_of_genome_editing_technologies.pdf)