[redacted]

Subject: FW: genome editing

From: [redacted](SANTE)
Sent: Wednesday, July 22, 2015 4:16 PM
To: [redacted]@vib.be'
Cc: [redacted](SANTE); [redacted](SANTE); [redacted](SANTE)
Subject: RE: genome editing

Dear [redacted],
Thank you for sending us your considerations on the legal interpretation of the GMO regulatory framework with regard to genome editing technologies.
Best regards

[redacted]
Policy Officer – Biotechnology

European Commission
Directorate-General for Health and Food Safety
Safety of the Food Chain Directorate
Biotechnology Unit
B-1049 Brussels/Belgium
[redacted]
[redacted]@ec.europa.eu

From: [redacted]@vib.be]
Sent: Monday, July 06, 2015 9:44 AM
To: [redacted](SANTE)
Cc: [redacted](SANTE)
Subject: RE: genome editing

Dear [redacted]

In relation to the regulatory status of organisms in which the genetic material has been altered using genome editing, I would like to share the following.

In my opinion the rationale for subjecting certain organisms to a prior risk assessment and thus subjecting them to regulatory oversight has always been and still is the following:

(1) Certain new technologies create possibilities to change the genetic material of organisms in such a way and to such an extent which may not have been possible before. The possibility to cross species barriers has traditionally been seen as an important point in that respect.
(2) There may be little or no experience with these new technologies and especially the organisms created by them, triggering a precautionary approach.

In Europe this has resulted in the formulation of a scope of the GMO regulatory framework that includes items on the basis of novelty of both process AND product and exempts items on the basis of familiarity. Novelty of a process is not enough to trigger the legislation (which is also very clear in the definition of LMO in the Cartagena Protocol). You also need

to have the formation of a new combination of genetic material. The directives dont regulate technologies. They regulate organisms in which the genetic material has been altered creating a new combination of genetic material using novel technology. And when it comes down to the exemption of organisms obtained through mutagenesis: many of the genome editing technologies are a form of mutagenesis. And mutagenesis is not further defined. Like classical mutagenesis they result in a small deletion, a basepair change or a frameshift mutation.

I think this is important for the legal interpretation of the current regulatory framework.

Kind regards,

[redacted]
VIB, Rijvisschestraat 120, BE-9052 ZWIJNAARDE, Belgium
T: [redacted] F: [redacted] M: [redacted]
E: [redacted]@vib.be