

Subject:

FW: genome editing

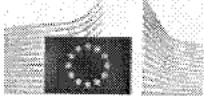
From: [REDACTED] (SANTE)
Sent: Wednesday, July 22, 2015 4:16 PM
To: [REDACTED]@vib.be'
Cc: [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE)
Subject: RE: genome editing

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 don't 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]

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