

From: [redacted] <[redacted]@sante.belgique.be>
Sent: 01 October 2018 14:26
To: [redacted] (SANTE); SANTE DIR 2001/18; SANTE CONSULT-E3
Cc: [redacted]
Subject: Follow up information regarding New mutagenesis techniques under GMO legislation

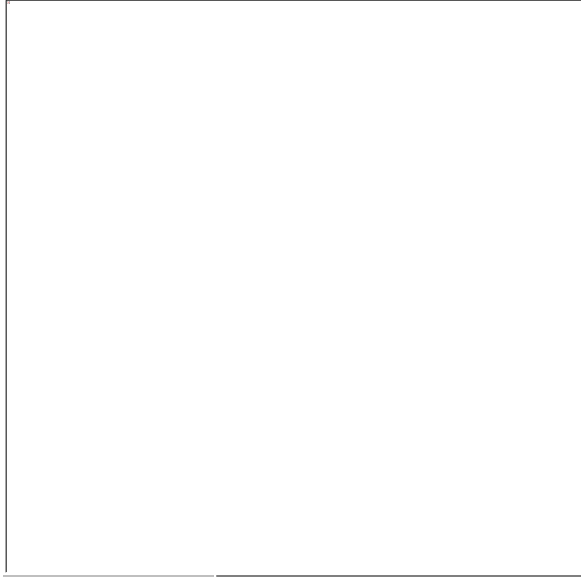
Dear [redacted] and colleagues,

Following your request during the Committee meeting of 11 september, you can find below information's about the present situation in Belgium :

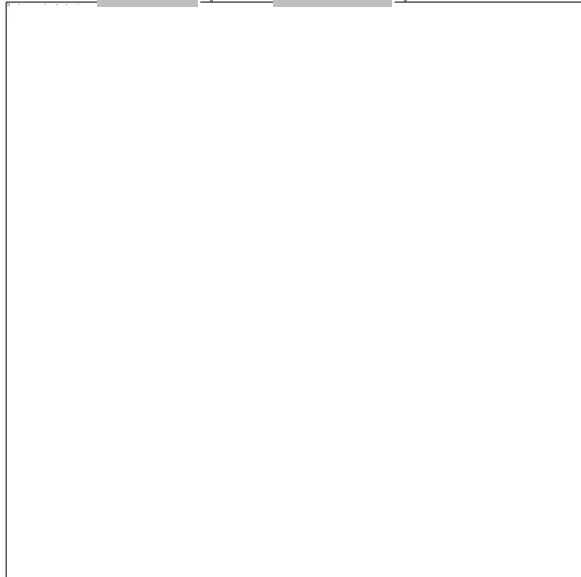
- Field trial with organism obtained by a new mutagenesis technique : **CRISPR Cas9 Maize notified under B/BE/18/V8**
- Clinical trial with organism obtained by a new mutagenesis technique : Phase 1/2 Study to Evaluate the Safety and Efficacy of a Single Dose of Autologous **CRISPR-Cas9 Modified CD34+ Human Hematopoietic Stem and Progenitor Cells (CTX001)** in Subjects With Severe Sickle Cell Disease. Approved by the FAGG-AFMPS on 17/08/2018 with a quality and regulatory recommendation. The IMP CTX001 was considered as a GMO falling within the scope of the GMO legislation. EudraCT number 2018-001320-19.
- There's no field or clinical trial with organism obtained by other new techniques.
- We received questions from stakeholders :
 - o One asked, after the publication of the ECJ arrest, if **PRRS resistant pork obtained by CRISPR Cas method in the US** are authorized or not in the EU. Of course, we answer that they're not and need an authorization before to be imported in the EU.
 - o End 2017 we received a question on the status of a **Cisgenic *Saccharomyces cerevisiae* strain**. Following our interpretation of the Directive 2001/18/EC, cisgenic yeast strains falls in the scope of GMO deliberate release legislation even if they could be excluded from the GMO contained use legislation (self-cloned microorganisms).
- Concerning the inscription of varieties to the national list, the technique used to obtain the variety is not a legal obligation. However, if the variety is GM, it's mentioned. In Belgium, no GM variety on the list (and we assume no variety obtained by new techniques).

As you can see and you already know, when we talk about New techniques the scope is larger than only plants and the CEJ arrest has impacts on other legislations (contained use, medicinal products...).

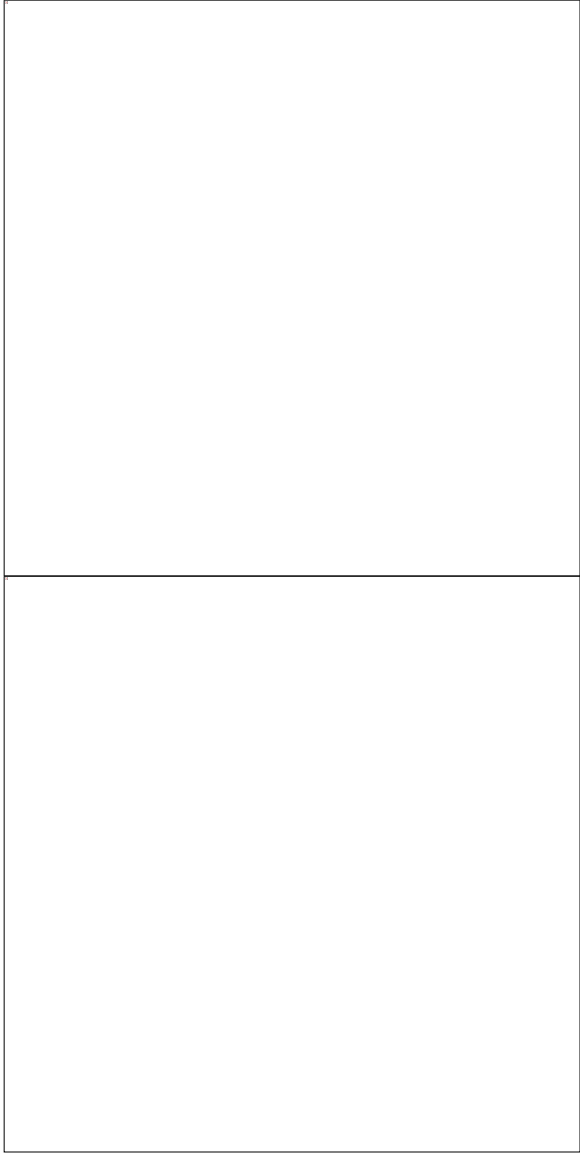
Best regards,



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