

**From:** [redacted]@sante.belgique.be>  
**Sent:** mercredi 19 décembre 2018 20:36  
**To:** SANTE CONSULT-E3  
**Cc:** [redacted]; [redacted]; [redacted] (SANTE); [redacted] (SANTE); [redacted] (SANTE)  
**Subject:** Follow up PAFF 03/12/2018 - new mutagenesis techniques  
**Attachments:** NRL\_GMO\_feedback\_NBT.pdf  
**Importance:** High

Dear,

At the latest PAFF meeting of December 3 2018, the Commission asked to member states to give some feedback regarding the NBT's and the ECJ decision on mutagenesis with deadline 20 December (extended to 20 January).

First of all, Belgium is working on a national position but it needs some times to achieve it at a political level.

However, here are a first batch of Belgian information's related to the questions raised by the Commission :

In annex, the Opinion of the Belgian NRL-GMO on the **consequences of ECJ ruling on enforcement and more specifically on the analytical tools needed for this**

The following questions were considered and also **Data collection and Data management** :

- Difficulties (including the impact on resources) for **analytical methods of detection** during official controls
- Examples of specific products or **situations for which the application of the GMO legislation (as clarified by the judgment of the European Court of Justice of 25 July) is problematic;**
- Ongoing **research and needs** related to NBTs
- **Problems** we also encounter in cases where the GMO is not obtained via an NBT

#### **Field trials**

A new notification for a field trial with a CRISPR maize mutant is planned in January 2019.

On that topic, we received a letter from stakeholder who is concerned because it's not possible to provide detection/identification methods for genome edited organisms with 100% detection/identification certainty. It's not possible to differentiate a mutation that occurs in the nature from a mutation obtained by classical mutagenesis or gene editing. It leads to difficulties to fulfill the requirements of part B deliberate release directive and they fears that some competent authorities try to reject notifications on that basis.

Concerning the inscription of varieties to the national list, the catalogue is not the solution for a form of "notification" of the varieties obtained by a new breeding techniques. Even if it is the common practice to declare the GM character of a variety listed in the catalogue, there is no legal obligation to do so. The only obligation comes from the GMO legislation. As organisms obtained by new mutagenesis techniques are considered as GMOs, and are not exempted, there's no need and no legal obligation to change something at the current situation. If the variety is GM, it's mentioned. It's also good to note that the catalogue legislation concerns only a list (large but finite) of agricultural or vegetable species. A large number of cultivated species escape this legislation,

including ornamental species. As far as the past is involved, it seems that it would be a good solution that the Commission address to the large seed companies, which hold the largest share of the European market, a demand to declare any variety obtained by a new technique... **It's not efficient to oblige each MS to make the same approach with the same companies** (Monsanto, Limagrain, Syngenta and others...). The Commission could also reiterate to these companies the requirement of prior authorisation of any new variety obtained by new mutagenesis techniques.

**Impact on Economy, trade and research :**

As you can read by following the links below, stakeholders are underlining that regulating genome edited organisms as GMOs has **negative consequences**.

<http://www.vib.be/en/news/Pages/European-scientists-unite-to-safeguard-precision-breeding-for-sustainable-agriculture.aspx>

<https://www.nature.com/articles/d41586-018-07166-7>

<http://www.nbtplatform.org/stories/ana-granados-chapatte>

[https://epsoweb.org/wp-content/uploads/2018/11/18\\_07\\_27\\_EPSO\\_ECJ-Ruling-Commentary-notes-by-EPSO-members-and-partners.pdf](https://epsoweb.org/wp-content/uploads/2018/11/18_07_27_EPSO_ECJ-Ruling-Commentary-notes-by-EPSO-members-and-partners.pdf)

I take the opportunity to inform you that there's also other problems that needs a common discussion during a joint Committee meeting of all GMO Competent authorities :

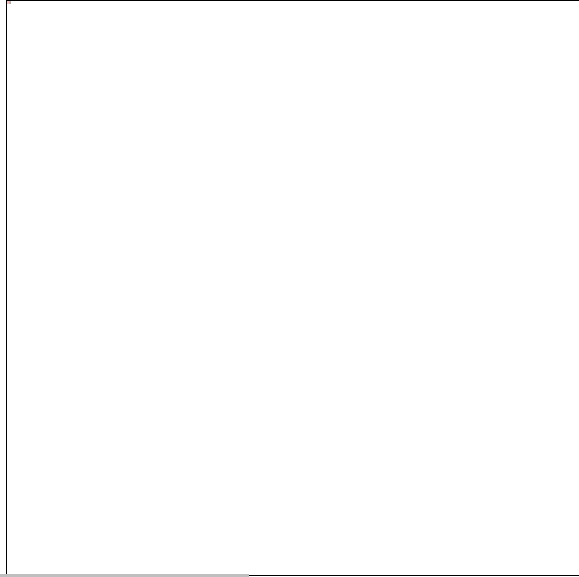
A **concrete example** is the case of **enzymes**. We were recently questioned about a difference in the interpretation of member states on the use **of asparaginase produced by GMM in organic** production. A company complained that concurrent in other MS are using asparaginase produced by GMM in organic production. It seems that the GMM is obtained by self-cloning and is exempted from the **Contained use directive 2009/41/EC** and then some member states says it's not a GMO and then the asparaginase is not "produced by a GMM" consequently they can use it in organic production. The problem is that they're GMOs as the **Regulation 834/2007** refers to the GMO definition of the **Directive 2001/18/EC** where no exemption exists for self-cloned organism. Another problem is that the Regulation 834/2007, article 9.1, doesn't allow the use of "produced by GMO's" but enzymes "produced by GMM" are not in the scope of the **GM Food Feed Regulation 1829/2003** (as stated in the "conclusions of the meeting of the wording party of Governmental experts on Food enzymes 20 october 2017") Then they're not labeled as GM and then they are a problem with the article 23 of regulation 834/2007 where it's referred to GM labelling to allow or not the organic labelling...

This example shows the complexity and problems faced when a same product can have different legal status depending on the legislation applied. It would be good to keep it in mind when applying different legislation when exactly the same product is produced by a NBT or by classical techniques.

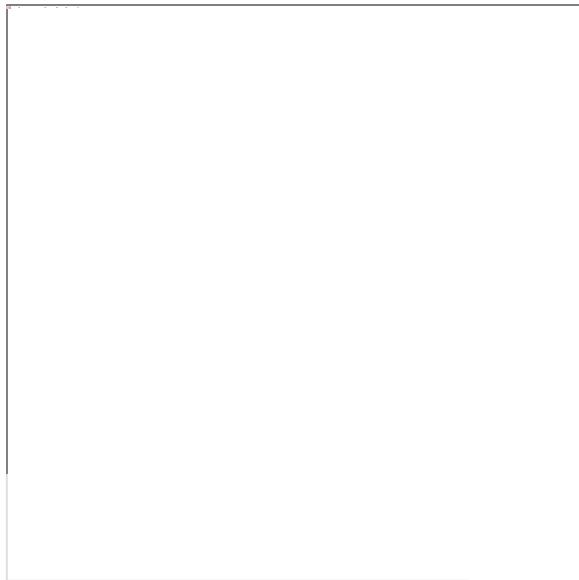
We're still reflecting and collecting information's then we keep the possibility to complete our answers in January 2019.

Wish you, your families and colleagues a merry Christmas and a happy new year !

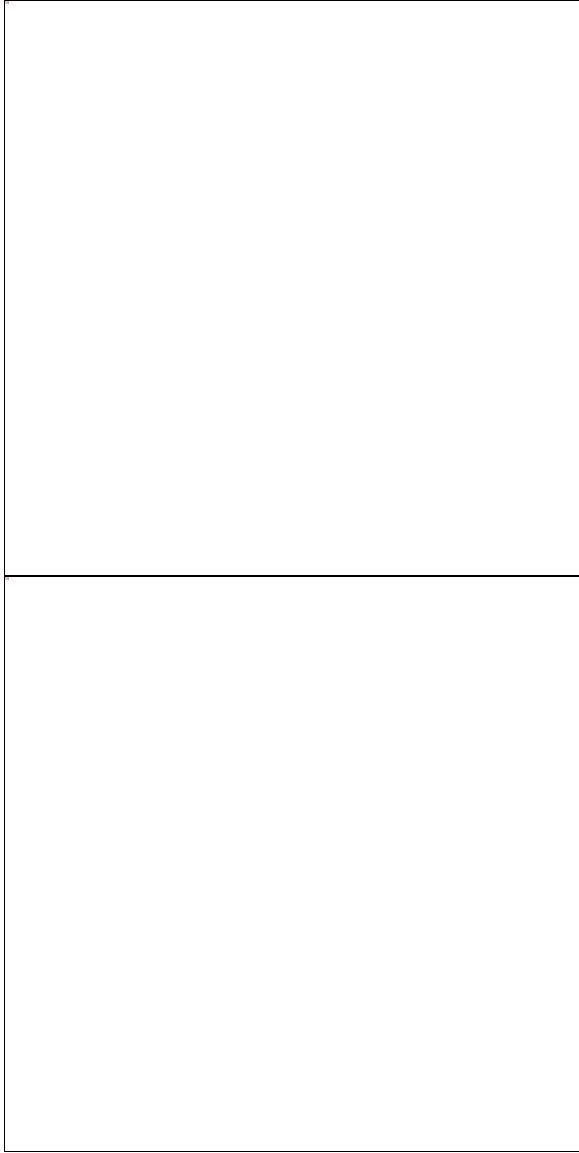
Best regards,



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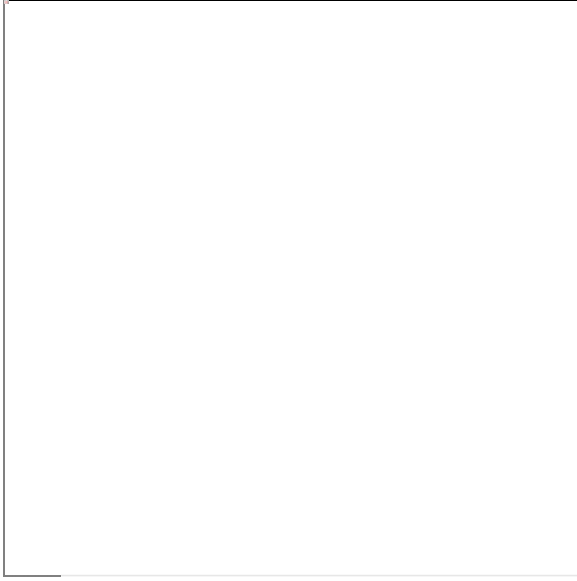


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