

BTO Meeting with Novozymes - 04/07/2019

Participants:

The meeting was requested by Novozymes as a follow-up to the previous meeting with SANTE on 25 September 2018 to discuss the ruling of the Court of Justice of the EU on mutagenesis and its impact on their business.

Novozymes presented their position on the regulatory framework for biotechnology innovation in the EU and provided the document in attachment.

Novozymes:

- Gave an overview of their area of activities on living microorganisms to produce enzymes, probiotics for food and feed uses, fertilisers, pesticides and detergents.
- Explained that with the existing legislation, the microorganism industry in the EU will miss many opportunities. Significant negative impact will also fall on their customer industry (e.g. feed and food, bioagriculture, detergents industry).
- Mentioned, as an example of missed opportunity, the possibility to use new techniques to knock-out antibiotic resistance genes.
- Referred to unfair competition with operators in non-EU countries, especially taking into account the difficulty or impossibility to distinguish certain microorganisms obtained with new techniques from those obtained with techniques of classical mutagenesis.
- Emphasised that techniques of classical mutagenesis are largely used in their sector.
- Considered that in order to implement the current legislation, traceability should be reinforced, however this is not always possible or effective.
- Informed that their initial plan to establish a GM research centre in Denmark, where Novozymes is based, was changed following the outcome of the ruling and the centre will now be set in the US.

- Explained that they consider the legislation should be revised to focus on the product rather than on the technique and to introduce a proportionate governance depending on the difference between the modified organisms and its natural counterpart.
- Concluded informing that they are part of a EU fermentation platform, which is planning to initiate a dialogue with the stakeholders, including the Commission and National authorities on the issue.

DG SANTE took note of the information provided, explained that no action is foreseen under this College of Commissioners and that further potential action is for next College. However DG SANTE confirmed its openness to have a dialogue on the matter with all relevant stakeholders.