

From: VINCIUNAS Arunas (CAB-ANDRIUKAITIS)
Sent: mardi 9 octobre 2018 19:06
To: BUCHER Anne (SANTE)
Cc: CHAZE Nathalie (CAB-ANDRIUKAITIS); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (SANTE); [REDACTED] (CAB-ANDRIUKAITIS); [REDACTED] (CAB-ANDRIUKAITIS) Art. 4(1)(b) (protection of personal data)
Subject: NBT Ares(2018)4704200

Dear Anne,

I refer to the note from Xavier Prats Monnet (Ares(2018)4704200 of 13/09/2018) on “New techniques in biotechnology – consequences of the court ruling and outstanding issues”

Our actions between now and the end of the college should be led by the principles of political discontinuity and proper enforcement of EU law.

The Court has confirmed that, according to current EU legislation, techniques of mutagenesis are classified as GMOs. This is very clear and will remain the case, failing a new legislation modifying the situation. The decision whether or not to take the initiative of proposing a new legislation will belong to the next Commission. This will be an important and politically sensitive decision and we should refrain from conveying to stakeholders the message that we are working in that direction, as we should not prejudge the future college decision. Our duty is to ensure EU law is implemented.

In the light of this, my answers to the specific questions in SANTE note would be the following:

- No objection to discussing the outcome of the ruling with MS and stakeholders, in so far as it is clear we are not engaging into seeking possible alternatives/flexibilities to EU law enforcement;
- Agree to mandate the JRC and EU network of GMO laboratories to work on methodologies to detect products obtained with mutagenesis,
- Agree to mandate EFSA to assess whether current risk assessment guidance is adequate,

[REDACTED]

Art. 4(2)
(legal
advice)
and Art.
4(3) (decision-
making
process)

- We have indeed requested the European Group on Ethics to identify ethical issues relating to gene editing, both in human health and agriculture contexts. We are interested in the outcome of this work that we agree SANTE should follow.

[REDACTED]

Art.
4(3)
(decision-
making
process)

However, having said all that, it is important to have a mapping of agricultural products resulting from new breeding techniques. During Commissioner's bilateral meeting with the Argentinian Secretary of State for agriculture, he learned that they will soon put on the market virus resistant potatoes, developed through NBT. I understand that research in relation to new mushrooms is quite advanced in the US. There are talks about climate change benefits from NBTs and so on. I would invite SANTE to engage into a scanning exercise about existing products or those currently in the pipeline. It is extremely difficult to communicate clearly about products we do not know. Launching such a fact finding exercise seems to me a urgent and necessary task.

Best,

Arūnas