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EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Director-General

Brussels,
SANTE/E3[redacted](2018)

Art. 4(1)(b) (protection of personal data)

NOTE TO MR ARŪNAS VINČIŪNAS,
HEAD OF CABINET OF COMMISSIONER ANDRIUKAITIS

Subject: **New techniques in biotechnology – consequences of the Court ruling and outstanding issues**

[redacted] Art. 4(1)(b) (protection of personal data)

This note describes the issues at stake following the CJEU ruling of 25 July in case C-528/16 on mutagenesis and provides proposals for follow-up actions.

1. Introduction

GMOs currently authorised under the EU GMO legislation have been obtained through established techniques of genetic modification leading to *transgenesis*[1]. New techniques of genetic modification were at an initial stage of development or did not exist when the GMO legislation was adopted in early 2000. Among these, *targeted mutagenesis* and *cisgenesis/intragenesis* are the most promising techniques.

The CJEU clarified the status of products obtained by techniques of *targeted mutagenesis*, concluding that, contrary to those from *classical mutagenesis*[2], they are not exempted from the GMO legislation. Therefore, GMO authorisation, traceability and labelling requirements apply to such products.

Prior to the CJEU ruling, several Member States authorised field trials with these products outside the GMO scope. The Commission had not issued an interpretation on the legal status of the products obtained by these new techniques.

While the legal status of these products is now clear, there are issues affecting implementation and enforcement of the legislation, which need to be addressed.

In addition, the legal status of products obtained by new techniques[3] that were not the subject to CJEU ruling C-528/16 remains to be clarified.

The table in the annex provides an overview of the regulatory status of each set of techniques.

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1 Transgenesis consists in the insertion in a recipient organism of genetic material from an organism with which the recipient organism could not reproduce naturally.

2 Classical mutagenesis: old techniques using radiation or chemicals to introduce mutations.

3 Cisgenesis/intragenesis, Reverse breeding, Agroinfiltration, RNA Dependent DNA methylation (RdDM). These techniques were initially identified by the New Techniques Working Group of Member States' experts. Grafting was also included in the analysis of the Working Group because the legal status of grafted plants is unclear when either the scion (the vegetative top part of the plant) or the rootstock (the rooted lower part) is GM. However, grafting is not a new technique and it is not modern biotechnology. It is therefore not addressed in this note.

2. Issues at stake

2.1. Detection methods/traceability/labelling:

Under the GMO legislation applicants must provide methods for the detection, identification and quantification of the products so that traceability can be ensured. Current analytical techniques are not fit for the detection and quantification of small sequence changes that can be obtained by *targeted mutagenesis* techniques. The products obtained with these techniques may not be distinguishable from similar unregulated products obtained with conventional techniques[4]. These limitations will hamper the authorisation of these products and enforcement by the competent authorities.

Problems related to enforcement may be partially overcome by implementing traceability through paper trail of the undetectable GM product, as it is currently the case with certain highly processed GM products[5]. This will however not allow detecting and quantifying adventitious and/or unintended presence of GM products in a batch of a non-GM commodity. Further, no testing method would be available to control potential traceability frauds. In addition, in the absence of a testing method, it would not be possible to control proper traceability and labelling of these products at import in the EU.

Suggested actions

- Discuss the outcome of the ruling and implementation/enforcement issues with Member States at the forthcoming Standing Committee meetings.
- Mandate the European Union Reference Laboratory for GM Food and Feed in the JRC (JRC-EURL GMFF) and the European Network of GMO Laboratories (ENGL) to assess the possibility for methodologies to detect products obtained with new mutagenesis techniques and distinguish them from similar products obtained with conventional techniques.
- Discuss the outcome of the ruling and implementation/enforcement issues with relevant stakeholders (e.g. subgroup of the Advisory Group on the Food Chain and Animal and Plant Health).

2.2. Risk assessment

The CJEU considered that "*the risks linked to the use of those new techniques/methods of mutagenesis might prove to be similar to those which result from the production and release of a GMO through transgenesis*". At the same time, several stakeholders, in particular scientists, claim that in principle *targeted mutagenesis* techniques are safer to use than *classical mutagenesis*. So far only transgenic products have been assessed and authorised for placing on the market under the GMO legislation, and the current risk assessment has not been tested by EFSA on products other than those obtained by *transgenesis*.

It is therefore important to assess whether *targeted mutagenesis* techniques pose novel hazards compared to conventional breeding and transgenic products and whether current

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4 [redacted] Art.4(3) (decision-making process)

5 The traceability and labelling obligations of the GMO legislation apply to food and feed products (e.g. oil) "produced from" a GMO, even if no DNA from the original product appears in the food or feed.

risk assessment guidance is adequate and proportionate to address possible risks related to new mutagenesis techniques.

Suggested action

- Mandate EFSA to assess whether *targeted mutagenesis* techniques pose novel hazards and whether current risk assessment guidance is adequate. This initiative would be consistent with previous requests made by the Commission to EFSA to provide an opinion on certain new techniques (*cisgenesis/intragenesis*, SDN3)[6].

2.3. Field trials in Member States

Member States (Belgium, Finland, Germany, Sweden, UK) that already gave permissions to carry out field trials prior to the Court ruling, must now ensure that field trials for any product from *targeted mutagenesis* techniques comply with the EU legislation and share this information with the Commission and the other Member States.

Suggested action

- Communicate requirements regarding field trials to the Member States at forthcoming Standing Committee meetings.

2.4. Other new techniques

[redacted]

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

With regard to detection method/traceability/labelling, *cisgenesis* and *intragenesis* do not pose particular problems, while the others raise some challenges of their own.

Field trials carried out so far in Member States for products from *cisgenesis* and *intragenesis* were approved under the GMO legislation and do not raise issues in this respect. The Commission is not aware of any field trials carried out in Member States for products from other techniques.

With regard to safety, EFSA has previously concluded that *cisgenesis* and *intragenesis* do not pose novel hazards and current guidance on risk assessment is applicable to them[6]. EFSA has not been requested to provide an opinion on the other techniques.

[6] EFSA Journal 2012;10(2):2561. EFSA Journal 2012;10(10):2943.

[redacted] Art. 4(2) (legal advice) and 4(3)

[redacted]

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

2.5. International dimension

In third countries, a number of products obtained from targeted mutagenesis are under development, such as resistant crops (to pests, disease, drought or salinity), crops with altered composition (absence of allergens, toxicants or increased nutritional value), increased yield farm animals (double muscle pigs), disease resistant animals (PRRS resistant pig, BSE resistant cattle), altered mosquitoes (prevention of transmission of vector borne diseases such as malaria, dengue, zika) and other applications in animals (hornless cattle, limited heat loss pigs, male only offspring). Commercially available and close to commercialisation products include non-browning mushrooms and potatoes, cold storage potatoes, high fiber wheat, improved quality alfalfa, high-oleic soybeans and herbicide tolerant oilseed rape

While some important trade partners have decided not to regulate and not to trace targeted mutagenesis products[8], such products can only be imported into the EU if they comply with the risk assessment and traceability requirements of the EU GMO legislation. [redacted]

Art. 4(1)(a) (protection of international relations

Furthermore, industry and research institutions have emphasized the negative effects of the ruling on EU agricultural research, innovation and competitiveness as developers are likely to operate in third countries with less stringent regulatory requirements.

Suggested action

- Communicate the immediate consequences of the CJEU ruling to trade partners.

3. [redacted]

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

[8] E.g. in the US, USDA does not regulate new mutagenesis plant varieties that are indistinguishable from those developed through traditional breeding methods, as long as they are not plant pests or developed using plant pests. Canada, Argentina and Chile have a product-based approach to decide on the regulatory status of new products on a case-by-case basis. Japan has not yet decided, but a government panel considers GM legislation should not apply to targeted mutagenesis. Australia is revising the existing GMO legislation with no clear position yet on new techniques.

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

[redacted]

[redacted]

9 [redacted]

[redacted]

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

3.2 Horizon scanning and ethical questions

In order to be prepared and ensure that the governance system continues to be adequate to new developments, a regular horizon scanning and trend analysis should be implemented, focusing on new techniques and synthetic biology applications.

In a number of cases these developments raise ethical questions, in particular for certain uses in animals and humans. In its statement on gene-editing from 2016[10], the European Group on Ethics in Science and New Technologies stated that ethical consideration needs to be given to all applications of gene editing, including the non-human applications.

[10] https://ec.europa.eu/research/ege/pdf/gene_editing_ege_statement.pdf#view=fit&pagemode=none

Suggested actions

- [redacted]

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

- Follow the work of the European Group on Ethics to analyse the ethical issues raised by new techniques, initiated by Commissioner Moedas in July.

4. Conclusion

[redacted]

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

I am looking forward to your comments on the suggested actions and the way forward on his matter.

[redacted]

Xavier Prats Monné

Art. 4(1)(b) (protection of personal data)

Annex

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[redacted], Mr M. Hudson,
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[redacted] (SANTE)

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[11] [redacted]

[12]

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