ANNEX

This annex is providing more detailed analysis of the issues presented in the note.

Mutagenesis – Court ruling of 25 July

Techniques of *random* or *classical mutagenesis* allow to introduce mutations by chemicals or by irradiation and have been used in plant breeding from the first half of the 20th century. The status of organisms produced by these techniques is undisputed: they are GMOs exempted from the GMO legislation.

More recent techniques of *targeted mutagenesis* allow to target mutations to specific sites of the genome and have been developed during the last two decades. On 25 July, the CJEU clarified that organisms obtained with such techniques are GMOs not exempted from the obligations of the GMO legislation. The CJEU considered that the precautionary principle demands that only techniques which have been "*used in a number of applications and have a long safety record*" are exempted; in view of the CJEU this is not the case of new mutagenesis techniques because they create risks which might prove to be similar to those from established techniques of genetic modification (i.e. *transgenesis*)[1].

Stakeholders have reacted very differently to the CJEU ruling:

- To date the only official reaction from a Member State has come from France, which welcomed the clarification given by the Court as an important step allowing competent authorities to ensure the protection of consumers and the environment in a harmonised manner and on the basis of the application of the precautionary principle.
- From the European Parliament, Greens/EFA welcomed the ruling as a victory of the precautionary principle, and against a corporate attempt to bypass EU GMO laws. They called the Commission to ensure the technical tools necessary to implement the ruling. Concerning safety of new techniques, Greens/EFA also raised the need for an evaluation by EFSA, the Science Advisory Mechanisms or by an ad-hoc expert committee. Statements from other Groups are not available yet.
- NGOs[2] have expressed satisfaction with the ruling, which is in line with their claims regarding the need to regulate all new techniques under the GMO legislation in order to ensure appropriate risk assessment and freedom of choice to consumers. They have called on the Commission to ensure appropriate implementation of the judgment and emphasised the need to develop methodologies for tracing the products.
- Industry[3] has emphasised the negative effects of the ruling on EU agricultural research, innovation and competitiveness and claimed that many SMEs will not be able to withstand the competition of foreign enterprises with negative implication on jobs, R&D and economic growth. Industry also encouraged public dialogue on new techniques in order to develop risk-proportionate policy approaches and to ensure that innovation in the EU keeps paces with that in other parts of the world.

[1] It is worth noting that the Court case was initiated by several NGOs which asked the French government to ban specifically herbicide-tolerant products obtained by targeted mutagenesis.
[2] Open letter to President Juncker from 16 organisations (Ares(2018)4185040)
[3] Press releases from Europabio, ESA, NBT Platform

- Most reactions from academic and research institutions[4] expressed disappointment with the ruling, emphasising the negative impact on innovation, scientific development and competitiveness in the EU. They highlighted that most research institutions and smaller companies will not be able to access the market and called for a new regulatory framework to ensure legal certainty and innovation.

Other new techniques

The available data in the scientific and grey literature, and in databases of experimental releases, as well as the input from stakeholders, seem to indicate that *cisgenesis* and *intragenesis*, in addition to mutagenesis, are the most promising techniques among those addressed below. The other techniques would be of lower importance.

1. Cisgenesis/intragenesis

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

With regard to detection method/traceability/labelling, *cisgenesis/intragenesis* techniques do not pose particular problems, as their products can be detected and identified.

Field trials carried out so far in Member States for products from *cisgenesis/intragenesis* were approved under the GMO legislation and do not raise issues in this respect.

With regard to safety, EFSA already analysed the applicability of current risk assessment guidance to *cisgenesis/intragenesis* and concluded that they do not pose novel hazards and that current guidance on risk assessment is applicable to them.

2. Agroinfiltration and reverse breeding

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

With regard to detection method/traceability/labelling, these techniques pose challenges when the alteration of the genetic material has disappeared in the final product. However if these

[4] EASAC in Euractive article: Industry shocked by EU court decision to put gene editing technique under GM law. Press release on expert reaction to Court of Justice of the European Union ruling that GMO rules should cover plant genome editing techniques.

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

products are considered out of the scope of the GMO legislation, traceability and labelling requirements would not apply.

The Commission is not aware of any field trials carried out in Member States for products from these techniques.

With regard to *safety*, EFSA has never been requested to provide an opinion on these techniques.

3. RNA dependent DNA methylation (RdDM)

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

With regard to detection method/traceability/labelling, these techniques pose some challenges since, although methods are available to determine DNA methylation, these methods have never been validated for official control purposes. However, the need for detection methods should be assessed in the light of the legal status of these products.

The Commission is not aware of any field trials carried out in Member States for products from these techniques.

With regard to *safety*, EFSA has never been requested to provide an opinion on these techniques.

Relevance of the techniques for developers

For agricultural applications, new techniques will likely be used by breeding companies to improve the genetic traits of plants, animals and microorganisms. They can be used for the same breeding objectives as conventional techniques or established GM techniques, with higher speed and applicable to a larger number of species. The plant breeding industry believes that what can take 8-12 years with conventional breeding, could take 2-4 years with new techniques.

Regarding *plants,* stakeholders have reported research activities on a number of traits such as resistance to disease, insects, fungi, blight and drought, tolerance to herbicide or increased nutritional value and nitrogen efficiency[7]. Research has focused on conventional GM crops such as maize and soya but industry and researchers claim that the lower cost of new techniques will make them economically viable for a much broader range of crops, including fruits and vegetables[8].

The plant breeding industry has undergone a trend of consolidation, from being dominated by relatively small breeders serving regional or national markets to being dominated by a few large agrochemical companies with global reach[9]. This trend has been driven by technological developments and thus benefited companies who first incorporated such developments.

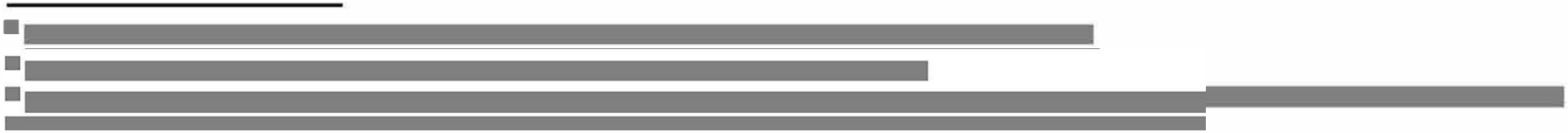
[7] For instance, one field trial in the Netherlands and Ireland of cisgenic potatoes resistant to late blight has shown that the application of fungicides could be reduced by 80-90% without compromising the yield.
[8] For instance, non-browning mushrooms and potatoes, cold storage potatoes, high fiber wheat, improved quality alfalfa, high-oleic soybeans, herbicide tolerant oilseed rape.
[9] The five largest seed companies went from controlling 9% of the global market in 1985 to 51% in 2012, and recent mergers and acquisitions in the industry indicate that the trend is continuing.

Regarding *animals*, breeders have expressed optimism about the use of new techniques to reduce disease[10], improve feed conversion ratios and improve animal welfare[11]. This would differ from the situation with established GM techniques, which to date did not have any significant penetration of the livestock and aquaculture sector[12].

Animal breeding has traditionally been dominated by small regional or national cooperatives of farmers which still play a role in some markets. However, accounts by industry stakeholders indicate that a trend of consolidation is also ongoing in the animal breeding sector[13].

[10] For example, research is ongoing to provide resistance to Porcine Reproductive and Respiratory Syndrome.
[11] E.g. to create hornless cattle.
[12] The only GM animal commercially available to date has been authorised by Canada (salmon presenting a trait that speeds up the growth to market weight).
[13] Genus Plc, leading pork and cattle breeding company, estimates that the top 3 companies control a 47% market share in pork breeding, and 27% in beef and dairy. The ownership of elite animals is also concentrating.

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



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