1.1. New Breeding Techniques

In 2016, *Conféderation Paysanne* and other French NGOs initiated judicial action against the French government, who decided not to revoke the provision of French law exempting mutagenesis techniques from the GMO requirements. The provision in the French law transposes the exemption in Directive 2001/18/EC on the deliberate release of GMOs applicable to organisms obtained by mutagenesis.

The NGOs asked the *Conseil d'État* to annul the government's decision and to introduce a moratorium on herbicide-tolerant oilseed rape varieties.

The NGOs claimed that mutagenesis should not be exempted from the GMO requirements, as not natural and not without harm to health or environment; the exemption in the French law breaches the precautionary principle and EU law and was adopted on the basis of an irregular procedure (no prior consultation of the *Haut Conseil des Biotechnologies – HCB*).

The French Ministry of Agriculture defended NGOs' action should be dismissed.

The *Conseil d'Etat* asked the Court of Justice of the European Union (CJEU) for an interpretation of the Directive.

The replies of CJEU (judgment of July 2018) to the questions can be summarised as follows:

1. *whether organisms produced by mutagenesis techniques are GMOs exempted from the GMO legislation:*
   yes, but only if they have conventionally been used in a number of applications and have a long safety record. Therefore, the GMO Directive is applicable to organisms obtained by mutagenesis techniques which have appeared or developed since the adoption of the Directive (2001)
2. *whether Member States can regulate exempted organisms*:
   yes, insofar as they comply with EU law, including free movement of goods.
3. *whether the exemption also applies to varieties obtained by new mutagenesis techniques included in the common catalogue set out by Directive 2002/53/EC (seeds directive) :*
   yes
4. *whether the validity of Directive 2001/18/EC can be called into question in light of the development of new mutagenesis techniques:*
   no reply as this question would only have been relevant if all organisms produced by mutagenesis were exempted.

Overall, to reach the above conclusions the CJEU considered that the risks linked to the use of new mutagenesis techniques "might prove to be similar" to those from the existing GMOs (established techniques of genetic modification). The CJEU also considered that exempting all organisms from new mutagenesis techniques from the GMO legislation would compromise the objective pursued by that legislation to protect human health and the environment and would not respect the precautionary principle.

Importantly, based on the interpretation provided by the CJEU, the *Conseil d'Etat* has now to provide a judgement on the particular case and to confirm (or not) an important issue (not clarified by CJEU), which will influence the scope of the EU Directive, if confirmed.

Whereas the random mutagenesis techniques are considered as exempted from the Directive, the *Conseil d'Etat* considered that *in vitro* random mutagenesis techniques (as opposed to *in vivo*) have been developed after the adoption of Directive 2001/18/EC. It also considered that all the herbicide-resistant seeds registered so far in the common catalogue of plant species have been produced with *in vitro* random mutagenesis. If this is confirmed by the *Conseil d'Etat*, those seeds and products, whether already marketed without any authorisation or to be placed on the market in the future, would no longer be exempted and would fall under the EU framework. It would create considerable market disturbance (withdrawal from market) and reactions from other Member States who do not share this view.

The timing of the *Conseil d'Etat* judgment is unknown.

Haut Conseil des Biotechnologies (HCB) recommendation

HCB published a recommendation on New Plant Breeding Techniques (NPBTs) in November 2017. The HCB envisages a framework based on the precautionary principle and the principle of proportionality. For crops developed with NPBTs that are not covered by Directive 2001/18/EC, a large majority of the HCB members favours a system of "intermediate" evaluation, i.e. in between the evaluation foreseen in Directive 2001/18/EC and the rules of the seeds legislation concerning the registration of varieties in the common catalogue or the national catalogue.

Work by JRC on detection

One of the most challenging issues as a follow up of the CJEU ruling is the impossibility to distinguish certain products produced with new mutagenesis techniques (and now covered by the GMO legislation) from conventionally-bred products. This results in difficulties to implement the legislation (detection methods compulsory in the applications, impossibility for MS to control, impossibility to label as the GMO content cannot be quantified). The JRC – who is the Reference laboratory for GMOs – is now working with the national laboratories on these issues. This difficulty should in principle trigger MS' readiness to revise legislation/provide for specific legislation. However up to now, no MS has made any such comment, probably because of the political sensitivity and the forthcoming European elections.

Lines to take

- Underline the importance of implementing the CJEU judgment and that France participates actively in the work of the JRC
- Inquire about their view on how to handle the new techniques, including those particularly sensitive in France (herbicide tolerant): is there any support to the HCB recommendation? Does France intend to launch a debate after the *Conseil d'Etat* ruling? What is their view on the EU legislation?
- Underline the importance that all Member States should become active in the discussions on the implementation of the CJEU judgement.
- In summary, reiterate the Commission's call to Member States to engage in dialogue on new biotechnologies in their countries and share their views on whether and how new biotechnologies should be governed at EU level.