VUB statement on the CJEU ruling on mutagenesis and the EU GMO regulation

The European Directive 2001/18/EC sets rules for the deliberate release of genetically modified organisms (GMOs). These rules require prior authorization for releasing GMOs in the environment for commercial or other purposes. The Directive makes such authorization dependent of an assessment of risks that such GMOs may present for human health and the environment and makes them subject to traceability, labelling and monitoring obligations. Exempted from the Directive are organisms produced by one or more of the techniques/methods listed below: (1) mutagenesis; (2) cell fusion (including protoplast fusion) of plant cells of organisms which can exchange genetic material through traditional breeding methods. "The background of these exemptions is that those organisms have been obtained through certain techniques of genetic modification which have conventionally been used in a number of applications and have a long safety record" (Recital 17 of the Directive).

In a ruling of 25 July 2018[1] the Court of Justice of the European Union (CJEU) specified that the mutagenesis exemption from the authorisation requirement is limited to GMOs developed through *conventional* mutagenesis techniques involving the use of radiation and chemicals, while it does not apply to more recent forms of directed mutagenesis involving genetic engineering.

Since this ruling there have been many public reactions from a variety of stakeholders. Some reactions welcomed the ruling, while other reactions called for further clarification of the ruling and/or changing the EU legislation. Reactions focused on the consequences of the ruling for the legal status of the release in the environment and commercialisation of organisms developed through genome editing.

Genome editing is a technique through which changes can be made at precise locations in an organism's genetic material. An additional relevant characteristic of this technology is that the so-called 'off target changes' on DNA level are much lower than is the case with conventional crossing and conventional mutagenesis. Currently this technique is mostly used to make small changes in genomes, changes that could also occur in a random way in nature. An example of that approach is making a few base pair changes in a gene that has undesirable effects, such as allergenicity, thereby 'knocking out' that undesirable gene. It is well established that genome changes in organisms generated by mutagenesis using conventional methods (involving the use of radiation and chemical) are random and *de facto* far less precise and unpredictable than when those genetic changes are obtained by state of the art gene editing technologies, including CRISPR/Cas or designer nucleases. Hence, based on these scientific arguments, VUB questions why the exemption from the authorisation requirement would be limited to GMOs developed through *conventional* mutagenesis techniques, while it would not apply to more recent forms of directed mutagenesis based on more precise gene editing technologies.

The Vrije Universiteit Brussel (VUB) recognizes that - because of its precision - genome editing has the potential to contribute significantly to improving human well-being and the environment, and the VUB emphasises the need to further explore the possibilities and opportunities of genome editing to improve human well-being, health care and food production, including the experimental release of organisms modified by genome editing. In this context, research at the VUB aims at gaining insight in fundamental life processes, but also at contributing to human and environmental welfare.

Genome editing can also be applied to make changes in an organism's genome that are not likely to occur in nature. The VUB recognises that the release in the open of organisms with genetic changes that are unlikely to occur in nature requires to address, on a case by case basis, the question whether those

[1] Case C-528/16, *Confédération paysanne e.a.*, ECLI :EU :C :2018 :583.

organisms are as safe as the non-modified organism from which they are derived with respect to human health and the environment.

From this perspective, the VUB supports regulatory systems that that aim to maximise benefits and minimise risks, including - in line with the precautionary principle a steady assessment and mitigation of identified risks of organisms developed through new biotechnologies, when they leave the controlled environment of laboratories. To ensure that regulatory systems accomplish this double objective, it is important that they are themselves regularly evaluated.

The VUB supports calls for further clarification of the scope of the Directive
as well as calls for a multidisciplinary evaluation of the EU regulatory system for the release of GMOs. Such evaluation should assess whether the regulatory system has kept pace with scientific and technological developments and include an evaluation of alternative ways to reach the same aims both in technological and in economic, societal and policy terms.

Regulatory aspects such as clarity, consistency, proportionality and workability in line with the EU's Better Regulation policy must also be considered. Such an evaluation should be conducted in a transparent fashion and involve all stakeholders and should henceforth provide reliable information as a basis for a further democratic discussion and legislative process about the risks that the European constituency collectively accepts to take or not. The evaluation process must be balanced, multidisciplinary and involve stakeholders, and it must also be efficient and allow for further responsible research and innovation.

The above evaluation should also be placed in broader context, such as the overall issues and aims of the production of food, feed and biomass. In that context it will be important to recognise that the future of agriculture is not a choice between 'either this or that technology', but rather the combination of the best components of all available practices and technologies, tailored to local needs, conditions and cultures. From that perspective the evaluation should also take into consideration all approaches to reach the same or even stronger aims. Similarly, it will be important to recognise the statement by the European Commission that in the interest of food security, no form of agriculture should be excluded, be it traditional, conventional or innovative.

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