Primary Food Processors

The Vital Link in the Food Chain

December 2019

PFP Statement on Court Ruling on mutagenesis
Clarity is much needed

The Primary Food Processors (PFP) take note of the ruling of the European Court of Justice (ECJ) on case C-528/16, issued in July 2018[1]. In that ruling, the ECJ established that organisms developed through "new" mutagenesis techniques are to be considered as genetically modified organisms (GMOs) as defined by Directive 2001/18 and are thus subject to its regulatory provisions[2]. Organisms obtained through conventional mutagenesis in a number of applications and have a "long safety record" are exempted, although Member States may establish specific rules.

A ruling that goes against the conclusions of the Advocate General

Surprisingly, the ECJ ruling contradicts the conclusions, in January 2018, of the Advocate General, who suggested that crops obtained by plant breeding technique 'mutagenesis' should not fall under laws restricting the use of genetically modified organisms (GMOs)[3].

A lack of clarity that creates uncertainty for the EU Primary Food Processors

One first problematic aspect is the very same fact that the ruling does not seem to address some key aspects such as the definition of 'conventionally used mutagenesis techniques' and of 'newer' mutagenesis techniques, as well as the powers effectively given to Member States. PFP sectors fear that such unspecified powers given to Member States may go as far as deciding that conventional mutagenesis is also to be subject to Directive 2001/18. This would mean that crop varieties lawfully being on the market for many years would potentially fall under the provisions of Directive 2001/18/EC. The lack of clarity also creates uncertainty on whether imported products are compliant and place on PFP members a responsibility that cannot be managed for the volumes needed to meet the EU demand.

A ruling in opposition to the situation elsewhere in the world

Overall, the regime suggested by the ruling is diametrically opposed to the one followed by many jurisdictions around the globe which do not intend to regulate (new) mutagenesis methods as GMOs.

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[1] (Reference for a preliminary ruling — Deliberate release of genetically modified organisms into the environment — Mutagenesis — Directive 2001/18/EC — Articles 2 and 3 — Annexes I A and I B — Concept of 'genetically modified organism' — Techniques/methods of genetic modification conventionally used and deemed to be safe — New techniques/methods of mutagenesis — Risks for human health and the environment — Discretion of the Member States when transposing the directive — Directive 2002/53/EC — Common catalogue of varieties of agricultural plant species — Herbicide-tolerant plant varieties — Article 4 — Acceptability of genetically modified varieties obtained by mutagenesis for inclusion in the common catalogue — Human health and environmental protection requirement — Exemption)

2 Directive 2001/18/EC of the European Parliament and of the Council of 12 March 2001 on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC - Commission Declaration, OJ L 106, 17.4.2001, p. 1–39

3Opinion of Advocate General Bobek, delivered on 18 January 2018(1) - Case C-528/16

This may result in a shift of raw materials production outside the EU and jeopardise availability of needed imports for the food and feed supply to Europe.

A ruling that today is not enforceable

The ruling is also difficult to implement and virtually impossible to enforce, given that many gene-edited products may be indistinguishable from products changed by natural processes or with conventional breeding techniques, as reconfirmed by the report of the Joint research Centre "Detection of food and feed plant products obtained by new mutagenesis techniques", published on 26 March 2019[4].

PFP welcomes the decision, adopted by the Council on 8 November, that the Commission should submit, by 30 April 2021, a study on the status of novel genomic techniques under Union Law and a proposal, if appropriate, in view of the outcomes of the study[5].

The potential of Plant Breeding Innovation

Mutagenesis, as well as other so-called Plant Breeding Innovation (PBI) methods, provides a promising potential for the PFP member companies as it may:

a) *Enhance plants disease resistance, thus reducing the need for pesticides;*

b) *Enhance plants tolerance to drought, and effectively adapt to climate change;*

c) *Assist in reducing plants allergenicity (the potential to cause an allergic reaction);*

d) Improve food quality and properties;

e) Contribute to enhanced food safety with varieties less prone to mycotoxins or other problems that pose a health risk.

Given the above, PFP believes that the ruling potentially puts the competitiveness of the sectors it represents at risk, and, most regrettably, fails to provide the much needed clarity on products obtained through new mutagenesis techniques (especially when those could also have been obtained with earlier breeding techniques or naturally). Clarity on the legal status of other recent PBI methods would also be desirable.

[4] "Detection of food and feed plant products obtained by new mutagenesis techniques", European Network of GMO Laboratories (ENGL); Report endorsed by the ENGL Steering Committee; Publication date: 26 March 2019 - https://gmo-crl.jrc.ec.europa.eu/doc/JRC116289-GE-report-ENGL.pdf

[5] Council Decision requesting the Commission to submit a study in light of the Court of Justice's judgment in Case C-528/16 regarding the status of novel genomic techniques under Union law, and a proposal, if appropriate in view of the outcomes of the study (Decision adopted at the 3724th Council meeting, Education, Youth, Culture and Sport, Education, Brussels, 8 November 2019 not yet published in the Official Journal of the EU).

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The **Primary Food Processors of the EU** (**PFP**) is composed by:

European Committee of Sugar Manufacturers (CEFS)
European Cocoa Association (ECA)
European Flour Milling Association (European Flour Millers)
European Vegetable Protein Association (EUVEPRO)
European Vegetable Oil and Proteinmeal Industry (FEDIOL)
European Starch Industry Association (Starch Europe)

PFP members process approximately 220 Million tons of raw materials (cereals, sugar beet, rapeseeds, soybeans, sunflower seeds, crude vegetable oil, cocoa products, starch potatoes…) employing over 120 000 people in the European Union.