MINISTRY OF
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Board for Gene Technology

European Commission
DG SANTE

ECJ RULING ON MUTAGENESIS TECHNIQUES

The Finnish Competent Authority for Directive 2009/41/EC, the Board for Gene Technology, decided on its meeting on October 17th 2018 to send a request to the Commission on the interpretation of the European Court of Justice (ECJ) ruling on July 27 2018 on case C-528/16. The case brought to ECJ concerned the legal status of mutagenesis techniques as stipulated in the Directive 2001/18/EC on the deliberate release of genetically modified organisms (GMOs) to the environment. The ECJ ruling does not refer to Directive 2009/41/EC on the contained use of genetically modified micro-organisms (GMMs). Therefore, it is currently unclear if the ECJ ruling applies also to contained use.

Part A of Annex II of Directive 2009/41/EC exclusively states that mutagenesis techniques are excluded from the Directive "on condition that they do not involve the use of recombinant-nucleic acid molecules or GMMs other than those produced by one or more of the techniques/methods listed below". Moreover, Directive 2009/41/EC does not contain anything similar to Recital 17 of Directive 2001/18/EC, which played a central role in the justifications of the ECJ Ruling.

During the past years - also after the ECJ ruling - the Board for Gene Technology has received several requests regarding the legal status of a certain type of mutagenesis, namely a situation where site-specific mutagenesis results in a deletion in the genome without leaving any foreign genetic material in the organism. As deletion mutagenesis is a commonly used technique in the basic research field within the Union, the Board now wishes to have a harmonized interpretation by the Commission Legal Service on the applicability of the ECJ ruling of such techniques in contained use.

The Board, which is also the Competent Authority for Directive 2001/18/EC, also wishes to have further clarifications as to the deliberate release of GMOs produced with mutagenesis techniques. The issues needing clarification are as follows:

- The ECJ ruling specifically mentioned chemical and radiation mutagenesis as techniques which are out of scope of Directive 2001/18/EC because they have a long safety record. Transposon mutagenesis is a technique that has been used for a long time e.g. for maize, fruit flies and bacteria. Should the ECJ decision be interpreted so that transposon mutagenesis is also out of scope, or is it just out of scope for these particular organisms?
- The ECJ ruling stressed the importance of a long safety record for the exempted mutagenesis techniques, which indicates that the safety of a mutagenesis technique should be evaluated after a certain time point. How is the Court Decision to be interpreted as to the time point and criteria for evaluating the safety of a mutagenesis method?

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- How should the ECJ ruling refocus the MS inspections on imported products, what are the most relevant analysis methods for new mutagenesis techniques in accredited laboratories and is there any estimate on the costs for supervision?
- How is the ECJ ruling interpreted as to the LMO definition according to the Convention of Biological Diversity (CBD); i.e. are the obligations of the Cartagena Protocol categorically applicable to organisms modified with novel mutagenesis techniques?
- How should the ECJ ruling be applied with regard to the regulations on the transportation of dangerous goods; i.e. does the Court Decision mean that all the organisms mutagenized with site-specific techniques should be treated as dangerous goods?

The Board also wants to address the recent COM proposal for a regulation on the making available on the market of CE marked fertilizing products (2018/C 346/46). The proposal aims in facilitating circular economy when it comes to fertilizing products. The Board has handled several requests by biotech companies wanting to recycle their Class 1 GMM fermenting waste through composting to produce fertilizers. In addition to the added value of the end product, composting is considered environmentally more sustainable than incinerating the wet biomass. Whereas the fermentation process itself is clearly contained use, marketing the composted product potentially still containing living GMOs would be subject to the Part C notification procedures laid down in the Directive 2001/18/EC. Such an expensive notification process is not likely to be a suitable option for the industry. As organisms produced with new mutagenesis techniques are an appealing tool for the biotech industry, the legal and practical problems about handling fermenting waste are likely to scale up after the ECJ Ruling. The situation is not due to specific national legislation and, hence, needs to be addressed at the EU level to be solved.

On behalf of the Board for Gene Technology