

Dear EC colleagues,

Following the ECoJ Ruling on 25th of July, 2018 and the GMFF PAFF discussion on 11th of September, 2018 the Slovak Republic would like to inform you, that:

The Department of Variety Testing (DVT), at the The Central Control and Testing Institute in Agriculture (CCTIA), has executed within the state variety trials the sunflower and the rapeseed varieties that had property of being resistant to active substances of certain herbicides (eg Imazamox). This property is registered under the trademark technology known as Clearfield, Clearfield Plus or Express Sunn. These technologies had been declared by the applicant as being prepared by **conventional breeding**, when the plant variety had been bred in order to obtain the property of being herbicide-tolerant.

Within the application for registration, the applicant stated that the varieties **are not a considered as GMOs** (according to the valid legislation – before the ECoJ Ruling took place).

The varieties are testes in the State variety trials. CCTIA does not check the specific herbicide tolerance in trials. Each variety is testes as classical variety and after registration is listed within the National catalogue and Common Catalogue. The DVT of CCTIA informs the applicants of this hybrid to send results of the set of specific in-field trials to confirm the herbicide resistance (results are according EPPO standards). Responsible person from the Department of Pesticides Registration of CCTIA obtains these documents and give the DVT information regarding the results. In case the whole documentation is in accordance with the laid down provisions, the tested variety is listed within „List of Clearfield varieties“ or „List of Express varieties“ on the CCTIA's web site <http://www.uksup.sk/oos-registre-a-zoznamy/> and farmers can use some specific herbicide for these varieties.

However, the DVT performs DUS tests (tests for the evaluation of the Distinctness, Uniformity and Stability and for the purpose to develop a description of the new variety), where the varieties are treated with the active substance in order to compare their morphological characteristics with the untreated varieties. No differences have been observed so far.

The DVT has developed a methodological guideline (in the Annex), where the registration procedure as well as the entry of the varieties belonging to Clearfield, Clearfield Plus or Express Sunn technologies to the national catalogue is explained.

Bearing this in mind, we would like to follow the legal grounds of the GMO legislation, so when application for registration will be put on the table, the applicants will have to determine which method (whether considered as GMO) was used in the breeding process. Also, the already registered varieties (belonging to Clearfield, Clearfield Plus or Express Sunn technologies) are going to be reappraised and the applicants will have to state the method used in the breeding.

Following the ECoJ Ruling only the products produced with new mutagenesis techniques should be considered as GMOs. However, at the moment the mutations induced by genome editing cannot be unequivocally distinguished from natural mutations. Moreover, mutations induced by genome editing technologies can also not be distinguished from those introduced by conventional mutagenesis techniques which have been incorporated in traditional breeding programs and are often not thoroughly documented. Therefore we have to believe the applicant, when stated that the variety proposed for state variety trial and registration is not GMO, as we are not able to affirm it at the moment by molecular testing.

Moreover, there are other techniques which belong to the scope of new breeding techniques (as listed in the publication of the JRC „New plant breeding techniques: state of art and prospects for

commercial development“ of 2011. These were also considered within the SAM advice on new techniques in agricultural biotechnology¹. The SAM advice states that there is heterogeneity within the NBT and some similarities between some NBT and some conventional breeding techniques as well as some established techniques of genetic modification. So logically, the ECoJ ruling may be applied also to other NBT. Bearing this in mind, we are of the opinion, that these techniques shall be listed on the Community level in order to avoid the fragmentation of the Common market. We would appreciate if Commission takes this into consideration in order to help the MSs to react to the ECoJ ruling in the same way and not to divergent from the GMOs legal framework.

Since the judgment is applicable only to the articles of Directive 2001/18 and Directive 2002/53, we do not expect to change the procedures set out in Directive 2009/41 on contained use of genetically modified microorganisms until the List of Techniques is adopted at Community level as suggested in the paragraph above.

¹ <https://ec.europa.eu/research/sam/index.cfm?pg=agribiotechnology> .