**Comments to draft opinion of the GMO panel "Applicability of the EFSA opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and 2 and oligonucleotide-directed mutagenesis"**

*Prof. Dr. Gabi Krczal on behalf of the Management Board of the Plant Biotechnology Society*

The Management Board of the Plant Biotechnology Society (PBS) welcome the opportunity to comment in close consultation with the "Wissenschaftlerkreis Grüne Gentechnik e.V." on the draft EFSA opinion "Applicability of the EFSA opinion on site-directed nucleases type 3 for the safety assessment of plants developed using site-directed nucleases type 1 and type 2 and oligonucleotide-directed mutagenesis. In the following the abbreviation PBS is always used for the " Plant Biotechnology Society e. V.". The PBS refers exclusively to the "Terms of Reference" and makes no comments on what else would be desirable with regard to the overall problems of the use of genome editing techniques.

General:

PBS supports the opinion and conclusions of the EFSA GMO Panel that plants whose genetic information has been altered by SDN-1, SDN-2 or ODM pose no fundamental new or additional risks to humans and the environment. There is no evidence of this in the scientific literature. The risk potential does not differ from that resulting from classic breeding or the classical mutagenesis processes. Thus, the safety assessment procedures used so far can be applied. However, a differentiated consideration must be performed as to whether the modified plant contains any exogenous DNA introduced during the genome editing process, which is often not the case with SDN-1, SDN-2 procedures and ODM. In case that no exogenous DNA is present in the plant genome, the corresponding assessment procedures must be adapted or the assessment must be based primarily on the product to be placed on the market. For gene edited plants, which could also result from natural or conventionally induced mutations, the mandatory 90-day feeding should be waived (Regulation (EU) No. 503/2013).

PBS agrees to the statement in lines169 – 172.

Editorial: Line 170: replace region by locus

PBS agrees with the statements in lines 173-175 and 345-347 on "off-target changes". Such effects also occur in breeding and classical mutagenesis methods and in a much higher number than in genome editing.

PBS agrees to the statement in lines 176 – 178. Where appropriate the terms "intragenes or cisgenes" should be introduced.

PBS agrees to the statements in lines 183 – 185. However it should be explained what is the real meaning of "lesser event-specific data" or some examples should be given.

PBS agrees to the statement in lines 306 - 308.

PBS agrees to the statement in lines 368 - 370.

PBS supports the conclusion

In detail:

Line 162: Add after segregation

Line 210: Brackets add after transgene, - cisgene, intragene

Line 237 add after a transgene – an intragene or a cisgene

Line 287: replace plant genome by – in the genome of the gene edited plant

Line 318: add after transgene  - intragene or cisgene

Line 383 add after:  transgene  - intragene or cisgene