

GMO high oleic acid soy doesn't raise health or environmental concerns, EU Food Safety Authority finds

Following the submission from Monsanto Company (hereafter referred to as 'the applicant'), the Panel on Genetically Modified Organisms of the European Food Safety Authority (hereafter referred to as the 'GMO Panel') was asked to deliver a scientific opinion on genetically modified (GM) soybean MON 87705 × MON 87708 × MON 89788 (hereafter referred to as 'the three-event stack soybean'). The scope of application is for the placing on the market of the three-event stack soybean for food and feed uses, import and processing.

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The molecular characterization, comparative analysis and the outcome of the toxicological, allergenicity and nutritional assessment indicate that the combination of the single soybean events and of the newly expressed proteins in the three-event stack soybean does not give rise to food and feed safety and nutritional concerns. In the case of accidental release of viable three-event stack soybean seeds into the environment, this would not raise environmental safety concerns.

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The three-event stack soybean is intended to confer an altered fatty acid profile (increased oleic acid content), and tolerance to dicamba and to glyphosate containing herbicides.

The GMO Panel evaluated the three-event stack soybean with reference to the scope and appropriate principles described in its guidelines for the risk assessment of GM plants and derived food and feed, the environmental risk assessment of GM plants and the post-market environmental monitoring (PMEM) of GM plants.

The GMO Panel considered the information available on the single soybean events, the three-event stack soybean, the scientific comments submitted by the Member States and the relevant scientific literature.

The single soybean events MON 87705, MON 87708 and MON 89788 were previously assessed by the European Food Safety Authority (EFSA) and no concerns on their safety were identified. No new safety issue was identified by updated bioinformatic analyses, nor reported by the applicant concerning the three single soybean events, since the publication of the respective scientific opinions. Consequently, the GMO Panel considers that its previous conclusions on the safety of the single soybean events remain valid.

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The GMO Panel concludes that there is a very low likelihood of environmental effects resulting from the accidental release of viable seeds from soybean MON 87705 × MON 87708 × MON 89788 into the environment.

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In addition, the GMO Panel considered the additional unpublished studies listed in Appendix B. This new information does not raise any concern for human and animal health and the environment regarding the three-event stack GM soybean.

The GMO Panel notes that in the context of this application the applicant did not provide a 90-day study on MON87705 soybean in line with the applicable legal requirements in the context of this three-event stack soybean application (i.e. no treatment with the intended herbicide was applied to MON 87705 soybean used to produce the test material). Therefore, the GMO Panel is not in the position to finalize the risk assessment of soybean MON 87705 × MON 87708 × MON 89788 under the current regulatory frame.

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