



Final Health and Environmental Risk Assessment of Genetically Modified Soybean MON 89788

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Authors' contributions

This work was carried out in collaboration between all authors. The opinion has been assessed and approved by the Panel on Genetically Modified Organisms of VKM. All authors read and approved the final manuscript.

Article Information

DOI: 10.9734/EJNFS/2021/v13i130366

Grey Literature

Received 14 October 2020
Accepted 19 December 2020
Published 06 March 2021

ABSTRACT

Soybean MON 89788 expresses the cp4 epsps gene from the plant pathogenic bacterium *Agrobacterium tumefaciens* (*Rhizobium radiobacter*) sp. strain CP4. The encoded enzyme 5-enolpyruvylshikimate-3-phosphate synthase (CP4 EPSPS) protein confers tolerance to the active herbicidal substance glyphosate. Updated bioinformatics analyses of the inserted DNA and flanking sequences in soybean MON 89788 have not indicated a potential production of putative harmful proteins or polypeptides caused by the genetic modification. Genomic stability of the functional insert and consistent expression of the cp4 epsps gene, have been shown over several generations of soybean MON 89788. With the exception of the intended changes caused by the trans-genetically introduced trait, data from several field trials performed in USA and Argentina show that soybean MON 89788 is compositionally, morphologically and agronomically equivalent

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to its conventional counterpart and other commercial soybean varieties. A sub-chronic feeding study with rats, as well as a nutritional assessment trial with broilers has not revealed adverse effects of soybean MON 89788. These studies indicate that soybean MON 89788 is nutritionally equivalent to, and as safe as conventional soybean varieties. The CP4 EPSPS protein produced in soybean MON 89788 does not show sequence resemblance to known toxins or IgE-dependent allergens, nor has it been reported to cause IgE-mediated allergic reactions. Soybean is not cultivated in Norway, and there are no cross-compatible wild or weedy relatives of soybean in Europe.

Based on current knowledge, the VKM GMO Panel concludes that with the intended usage, there are no discernible safety concerns associated with soybean MON 89788 regarding human or animal health or to the environment in Norway.

Keywords: *GMO; soybean (Glycine max); MON 89788; EFSA/GMO/NL/2006/36; herbicide tolerance; cp4 epsps; food and feed safety; environmental risk evaluation; Regulation (EC) No 1829/2003; VKM; risk assessment; Norwegian Scientific Committee for Food Safety; Norwegian Environment Agency.*

Available: <https://vkm.no/download/18.2994e95b15cc545071614cc2/1498139869035/bced6eafb7.pdf>

ISBN: 978-82-8259-164-5

NOTE:

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Suggested citation: VKM (2015) Food/feed and environmental risk assessment of herbicide tolerant genetically modified soybean MON 89788 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (EFSA/GMO/NL/2006/36). Opinion of the Panel on Genetically Modified Organisms of the Norwegian Scientific Committee for Food Safety, ISBN: 978-82-8259-164-5, Oslo, Norway.

COMPETING INTERESTS

Authors have declared that no competing interests exist.

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