



Final Health and Environmental Risk Assessment of Genetically Modified Soybean MON 87701

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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.

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Grey Literature

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ABSTRACT

Soybean MON 87701 expresses the cry1Ac gene from *Bacillus thuringiensis*. The encoded Cry1Ac protein confers resistance against specific lepidopteran pests. Updated bioinformatics analyses of the inserted DNA and flanking sequences in soybean MON 87701 have not indicated a potential production of harmful toxins and allergens or polypeptides caused by the genetic modification. Genomic stability of the functional insert and consistent expression of the cry1Ac gene, have been shown over several generations of soybean MON 87701. Data from several field trials performed in USA, Canada, Chile and Argentina during 2005-2006 show that soybean MON 87701 is compositionally, morphologically and agronomically equivalent to its conventional counterpart and other commercial soybean cultivars. Subchronic feeding studies with rats as well as nutritional assessment with broilers have not revealed relevant adverse effects of MON 87701. These studies

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indicate that MON 87701 is nutritionally equivalent to and as safe as conventional soybean cultivars. The Cry1Ac protein produced in soybean MON 87701 do not show sequence resemblance to known toxins or IgE-dependent allergens, nor has the whole GM plant been reported to cause changes in IgE-mediated allergic reactions in patients reactive to soybean or in non-ectopic control individuals. Soybean is not cultivated in Norway, and there are no cross-compatible wild or weedy relatives of soybean in Europe. Based on current knowledge and considering the intended uses, which exclude cultivation, the VKM GMO Panel concludes that soybean MON 87701 with the Cry1Ac protein:

- Is compositionally, morphologically and agronomically equivalent to its conventional counterpart and other commercial soybean cultivars
- Is unlikely to introduce a toxic or allergenic potential in food or feed compared to conventional soybean cultivars
- Is nutritionally equivalent to and as safe as its conventional counterpart and other conventional soybean cultivars
- Does not represent an environmental risk in Norway.

Keywords: *GMO; soybean (Glycine max); MON 87701; EFSA/GMO/BE/2010/79; insecticidal properties; Cry1Ac; food and feed safety; environmental risk evaluation; Regulation (EC) No 1829/2003; VKM; risk assessment; Norwegian Scientific Committee for Food Safety; Norwegian Environment Agency.*

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COMPETING INTERESTS

Authors have declared that no competing interests exist.

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