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# **Final Health and Environmental Risk Assessment of Genetically Modified Soybean 356043**

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## **Authors' contributions**

*This work was carried out in collaboration among 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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## **ABSTRACT**

Soybean 356043 expresses both the *gat* gene from the soil bacterium *Bacillus licheniformis* and the *gm - hra* gene, an optimised form of the endogenous acetolactate synthase (*als*) coding sequence from soybean (*Glycine max*; *gm*). The encoded GAT4601 protein, glyphosate acetyltransferase, confers the ability to inactivate the active herbicidal substances glyphosate and glyphosate-ammonium to N-acetyl glyphosate, which does not have herbicidal activity. The encoded GM-HRA protein confers increased tolerance to the active, ALS-inhibiting, herbicidal substances chlorimuron, thifensulfuron and sulfonyleureas. Bioinformatics analyses of the inserted DNA and flanking sequences in soybean 356043 have not indicated a potential production of putative harmful

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proteins or polypeptides caused by the genetic modification. Genomic stability of the functional insert and consistent expression of the *gat* gene, have been shown over several generations of soybean 356043. Data from several field trials performed in USA, Canada, Chile and Argentina during 2005-2006 show that soybean 356043 contains higher levels of especially the acetylated amino acid N-acetyl aspartate, but also N-acetyl glutamate and the odd-chain fatty acids heptadecanoic, heptadecenoic and heptadecadienoic acids, in addition to expression of the newly expressed proteins. Otherwise the soybean 356043 is compositionally, morphologically and agronomically equivalent to its conventional counterpart and other commercial soybean cultivars. The acetylated amino acids and odd-chain fatty acids are normal constituents of plant and animal-derived foods and feeds, and an in-depth toxicity and intake assessment did not reveal safety concerns regarding consumer intake at the levels present in soybean 356043. Sub-chronic feeding studies with rats, repeated-dose toxicity studies with mice, as well as nutritional assessment trials with broilers and laying hens have not revealed adverse effects of soybean 356043. These studies indicate that soybean 356043 is nutritionally equivalent to and as safe as conventional soybean cultivars. The GAT4601 and GM-HRA proteins produced in soybean 356043 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 356043 with the GAT4601 and GM-HRA proteins:

- Is – with the exception of the novel traits and resulting increased content of the acetylated amino acids NAA and NAG, and the odd-chain fatty acids heptadecanoic, heptadecenoic and heptadecadienoic acids – compositionally, morphologically and agronomically equivalent to its conventional counterpart and other commercial soybean cultivars
- Are unlikely to introduce toxic or allergenic potentials 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); 356043; EFSA/GMO/UK/2007/43; herbicide tolerance; gat4601; gm – hra; 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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