Safety Assessment RP1372 Genetically Modified 73496 Oilseed rape

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Summary

Following the submission of application RP1372 from Corteva Agrisciences LLC Represented by Corteva Agriscience UK Limited, to the Food Standards Agency (FSA) under assimilated Regulation (EC) No. 1829/2003, FSA/FSS (Food Standards Scotland) have undertaken a safety assessment on genetically modified 73496 oilseed rape. To support the safety assessment by FSA/FSS, the Advisory Committee on Novel Foods and Processes (ACNFP) provided advice to FSA/FSS on the data submitted for the authorisation of genetically modified 73496 oilseed rape, as outlined in this document. The advice of the ACNFP has been taken into account in this safety assessment which represents the opinion of FSA/FSS on the safety of genetically modified 73496 oilseed rape.

73496 oilseed rape is modified by the addition of the gat4621 (glyphosate acetyltransferase) gene cassette (a shuffled variant of three gat genes from Bacillus licheniformis). Glyphosate inhibits the enzyme enolpyruvylshikimate-3-phosphate synthase (EPSPS), which is involved in the biosynthesis of aromatic amino acids. The expression of the GAT4621 protein, encoded by the gat4621 gene in 73496 oilseed rape renders the crop tolerant to the herbicidal active ingredient glyphosate by acetylating its secondary amine. This generates N-acetyl glyphosate, which has no herbicidal activity.

Canada, China, the EU and India are the top oilseed rape producers with the crop also being grown in Australia, South America and the United States. The EU is the largest producer of oilseed rape. Oilseed rape seed is not commonly consumed without processing and its fractions have different uses for humans and livestock. The seed is crushed to harvest the high-quality oil, used in human diets for shallow, home or pan frying, cooking and dressing. The animal feed industry uses the by-product of the crushing process as a source of protein. The scope of the application is for the authorisation for import, processing, and food and feed use of glyphosate tolerant 73496 oilseed rape. The application does not cover cultivation and therefore no 73496 oilseed rape will be grown in the UK.

In providing its scientific advice, the ACNFP considered data provided as part of application RP1372. The molecular characterisation determined that 73496 oilseed rape contained a single, intact copy of the T-DNA at a single locus, with the presence of a disrupted triose phosphate transporter (tpt) gene near the 5’ border of the insert flanking regions. From the analysis of Bioinformatic data it emerged that a fairly large rearrangement has occurred at the locus of recombination which could have caused the disruption, but from sequencing data it is not possible

to confirm if this rearrangement is a consequence of the transformation event, or if it was already in the progenitor line, as the applicant does not have the parental sequence. The ACNFP concluded that it was not necessary to request parental sequencing data and that no safety concerns arose from the rearrangement. However, other tpt homologues in the oilseed rape genome are likely to compensate at least partially for the loss of the disrupted tpt gene. Moreover, as 73496 oilseed rape is commercialised as a hybrid product containing one intact and one disrupted copy of the tpt gene, the phenotypic and agronomic effect of the tpt disruption near the 73496 event is likely negligible. Bioinformatics analyses of the insert and flanking regions (including the junctions between them) found no homology with known toxic or allergenic proteins and found no sequences that could lead to horizontal gene transfer. Genetic stability of the transgenic locus, and phenotypic stability of transgenic protein expression were both confirmed. The field trials (including locations and management practices) to produce test materials for the comparative analysis were considered appropriate, and no differences between the 73496 oilseed rape and the conventional counterpart or the non-GM reference varieties that would raise safety concerns were observed. Studies on the newly expressed protein found no evidence of potential toxicology. The studies were performed using bacterially-produced protein, and the ACNFP considered that these proteins were equivalent to plant-produced proteins. Toxicological feeding studies indicate that there are no safety concerns for animal and human health. The homology searches performed through BLASTP confirmed that GAT4621 protein shows no similarity to known allergens, toxins or antinutrients. An independent, outside contractor assessed the outcomes and methodologies of all bioinformatic analyses and was satisfied that the methods and results were satisfactory.

The ACNFP concludes that considering the nature of the introduced traits, the lack of differences in the agronomic and compositional analyses, and the proposed levels of exposure, there is no evidence that the import, processing, and food and feed use of 73496 oilseed rape would raise any safety concerns. The ACNFP concludes that 73496 oilseed rape is as safe as its conventional counterpart.

Safety assessment

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