

Omega-3 canola offers essential nutrients for human and animal health, requiring a more balanced, trait-based approach in safety assessment

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Abstract

Omega-3 long-chain polyunsaturated fatty acids (ω 3-LCPUFA) are nutritionally important for both human and animal health, yet the marine sources of these nutrients are limited. Canola has a high oil content with efficient production costs, making it an ideal candidate for stable and sustainable ω 3-LCPUFA production. After more than a decade of effort, omega-3 canola events have been successfully developed through genetic engineering, including Nuseed's DHA canola. However, gaining regulatory approvals for such novel nutritional traits has a unique set of challenges. Unlike the single-gene input traits, such as herbicide tolerance or insect resistance, nutritional traits are generally more complex involving multiple genes, making them more challenging and time-consuming to characterize. Next generation sequencing technologies have proven to be very efficient and can be employed more effectively than traditional southern blot analysis alone in characterizing complex events. Protein safety evaluation presents another challenge. The introduced proteins in DHA canola are intractable transmembrane desaturases and elongases, making them extremely difficult to quantify, isolate and purify for protein characterization. In addition, low-level expression and the inability to concentrate and express identical proteins in heterologous systems make performing toxicity studies using isolated protein almost impossible. Therefore, safety assessment of these proteins requires adaptation, and alternative tiered approaches should be accepted to build a weight-of-evidence argument. Moreover, some regulators in various jurisdictions conduct risk assessment without considering the nature of the trait or intended uses, adding unnecessary burdens and delaying approvals. This presentation calls for balancing experimental evidence and trait-based regulations to support scientifically sound safety assessment for innovative nutritional traits, thereby benefiting societal needs sooner by promoting the adoption of sustainable food and feed innovations.

Key words: ω 3-LCPUFA, nutritional traits, DHA canola, safety assessment, trait-based regulation