Genetically engineered eucalyptus expressing proteins from *Bacillus thuringiensis* for insect resistance: a risk assessment evaluation perspective

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Abstract: With around 7.5 million hectares planted, *Eucalyptus* is the main forest species in commercial use in Brazil. In addition to exotic pests, eucalyptus trees are also attacked by numerous native insects in the Americas that have adapted to Eucalyptus consumption, causing significant forest productivity and economic losses. The primary lepidopteran pest of *Eucalyptus* is the *Thyrinteina arnobia* (Lepidoptera: *Geometridae*), commonly known as the brown caterpillar. Its high reproduction rate on various hosts, voracity, and dispersal capabilities provides perfect conditions for outbreaks, especially in periods of drought when the population of natural enemies generally decreases. In a pioneering initiative, FuturaGene, the biotech division of Suzano, has developed an insect-resistant (IR) eucalyptus expressing Cry pesticidal proteins targeting lepidopteran insect pests. The insect-resistant eucalyptus expresses genes derived from *Bacillus thuringiensis* (*Bt*), which is a ubiquitous soil bacterium that has proven to be a rich source of insecticidal proteins, which are selective and generally active against insects within a specific taxonomic order. A science-based safety assessment was conducted on the IR eucalyptus prior to submission to the National Committee for Biosafety (CTNBio)_in Brazil, for approval to commercialize the variety. The safety assessment addressed allergenicity; acute oral toxicity; sub chronic toxicity; substantial equivalence with conventional comparators, and environmental impact. Results from biochemical, physicochemical, and in silico studies indicate that the Cry pesticidal proteins are unlikely to be either allergenic or toxic to humans and animals. Moreover, toxicological and field studies support that IR GM eucalyptus, is as safe as the conventional clone in its potential for invasiveness, gene flow to wild and weedy relatives, or impact on non-target organisms. Results of our studies indicate that the IR eucalyptus is safe for humans, animals, and the environment.

Key words: eucalyptus, insect, insect resistance (IR), GM (genetic modified), CTNBio