A Successful Platform for Risk Assessment of Brazilian-Produced Biotech Proteins

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INTRODUCTION. In the last years, several Brazilian research groups have dedicated to activities of prospecting and characterization/improvement of the biological activity of proteins potentially useful for biotech applications. Nevertheless, there are just few or no information on safety for human/animal consumption or environmental application of these novel peptides/proteins. It is known that the risk assessment of biotech products is a crucial part for approval of their commercial release. Besides, an early risk assessment of candidate proteins has been indicated since it may avoid huge economic and time consuming efforts, as well as may help to guide modifications in the protein structure in order to free it of a potential risk. **OBJECTIVES**: This study aimed to build and assess a multi-test platform for early risk assessment of peptide/protein candidates to biotechnological uses. **MATERIAL AND METHODS:** In a case-by-case approach, different peptide/protein samples were submitted to a battery of *in silico*, *in vitro* and/or *in vivo* tests. The protein samples assessed were: Cry8Ka1, Cry8Ka5 and CryIa12 insecticidal proteins from *Bacillus thuringiensis*; *Mo*-CBP$_3$ antifungal protein from *Moringa oleifera*; JBU and JBTX insecticidal/antifungal proteins from *Canavalia ensiformis*; *Mo*-CBP$_4$ antiinflammatory protein from *M. oleifera*; and *Calotropis procera* proteases. These proteins are intended to be used in very different biotech products such as insect-resistant transgenic crops. The tests covered the history of safe use, amino acid sequence similarity analysis, simulated gastrintestinal digestion, cyto- and genotoxicity and antimicrobial analysis, *in vitro* toxicogenomics, and/or acute and sub-chronic animal exposure assays. **DISCUSSION AND RESULTS:** The results observed for Cry proteins showed a great certainty of safety, whereas those for *Mo*-CBP$_3$ showed an allergenic potential. The other protein samples are still under analysis. **CONCLUSIONS:** the created multi-test platform was very efficient to detect potential risks of novel proteins, as well as guarantee the safe use of other biotech proteins.

Keywords: multi-test platform, food safety, recombinant proteins.

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