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Bt brinjal: A case study in biosafety risks to plant biodiversity

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Several transgenic disease-resistant crop forms have been developed for commercial use across the world. Most of these rely on genetic transformation brought about by genes substituted from the soil-borne microorganism *Bacillus thuringiensis* ("*Bt*")which confer the ability to produce "Cry" proteins which are lethal to arthropods such as lepidopterans. In the interests of biosafety certain environmental risk assessments should be undertaken, so that the environmental consequences of commercial production can be determined. Such consequences include transgene transfer to related species of spiny solanums. If *Bt* transgenes become introgressed into these species the resultant hybridsmay constitute a serious riskto plant biodiversity. This arises from the combination of pest resistance with the inherent weedy nature of this group. The resultant situation could generate aggressive weeds with a tendency to become invasive particularly in the vicinity of farms in South and South-east Asia on which *Bt* brinjalis cultivated. The implications for ecological equilibrium will thus present a threat to plant biodiversity.In order to make thorough assessments of these riskscertain essential background information on the precise biological taxonomic and floristic characteristics of the transformed species and its cultivated and wild relatives must be amassed. This should encompass information on reproductive characteristics and phenology; interfertility relationships between the transformant and related species as well as between the relatives themselves; correct nomenclature, identification and systematic placement and floristics of wild relatives. Thorough and concise investigations of the possibility of transgene transfer to either untransformed crops of the same species, sympatric wild relatives orclosely-related crops grown sympatrically can hence be undertaken. The potential consequencesfor plant biodiversity of transgene transfer should not be underestimated, and detailed long-term studies are vital for a balanced assessment of risks. The history of the development of *Bt* brinjal shows that whilst certain studies have been of benefit, they have been limited in nature. An attempt is made here to contribute towards a fuller understanding of essential background information on *Bt* brinjal.

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QbD for downstream process development of CIGb 550-E7, active pharmaceutical ingredient of HPV candidate vaccine

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Nowadays the biopharmaceutical sector is focuses on the need to implement quality systems based on the real time data and deeper understanding of manufacturing process since the development stage. Quality by Design seems to be the "good choice" due to its manufacturing design philosophy that increases the upfront experimentation and continuous monitoring in order to the establishment of the design and knowledge space where the control process and good quality product will be a guaranty. The CIGB 550-E7 is a fusion protein comprising the HPV16 E7 antigen fused to a cell penetrating and immunostimulatory peptide which corresponds to the carboxy terminal region of LALF 32-51. Previously we demonstrate that CIGB 550-E7 induces a potent antitumoral response against E7 expressing tumors, therefore could become a promising vaccine candidate for the treatment of HPV 16 related malignancies. This talk describe the process development to obtain a final product with CIGB 550-E7 as an active ingredient based on the implementation of QbD. It helped us to build the knowledge space and get information about critical, non- critical attributes and process parameters and also encompasses the design space and normal operating ranges as well as areas where the CIGB 550-E7 it is known that unacceptable product is produced.

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